Product Assessment Report

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

CAID GRAIN'TECH

LIPHATECH SAS

September 2012

Internal registration/file no:	PB-11-00046
R4BP no:	2011/4329/11206/FR/AA/20567
Authorisation/Registration no:	Prof: FR-2013-0002 / General public: FR-2013-1001
Granting date/entry into force of authorisation/ registration:	4th March 2013
Expiry date of authorisation/ registration:	30th June 2016
Active ingredient:	**CHLOROPHACINONE**
Product type:	**14**

Competent Authority in charge of delivering the product authorization: French Ministry of Ecology

Department for Nuisance Prevention and Quality of the Environment
Chemical Substances and Preparation Unit
Grande Arche, Paroi Nord
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Authority in charge of the efficacy and risk assessment:

Anses – French agency for food, environmental and occupational health and safety
Regulated Products Directorate
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1 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

1.1 Applicant

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Postal Code:	47480
Country:	FRANCE
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Fax:	+ 33 553 479 501
E-mail address:	billeretm@desangosse.com

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Mikaëline BILLERET
Function:	Regulatory manager
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City:	Pont du Casse
Postal Code:	47480
Country:	FRANCE
Telephone:	+ 33 553 698 190
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1.2 Proposed authorisation holder

Company Name:	LIPHATEC SAS
Address:	Bonnel BP3
City:	Pont du Casse
Postal Code:	47480
Country:	FRANCE
Telephone:	+ 33 553 698 190
Fax:	+ 33 553 479 501
E-mail address:	billeretm@desangosse.com
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	yes

1.3 Information about the product application

Application received:	28/06/2011
Application reported complete:	26/07/2011
Type of application:	Product authorisation
Further information:	-

1.4 Information about the biocidal product

1.4.1 General information

Trade name:	CAID GRAIN'TECH (former CAID APPATS)
Manufacturer's development code number(s), if appropriate:	CLOBL0,0050_05F_LR0191_02 Red Wheat
Product type:	PT14 - Rodenticide
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Active substance's identity and content: Chlorophacinone 0.005% w/w No substance of concern
Formulation type:	VIII.3.1 Grain bait
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):	Yes CAID APPATS : n°6100387 No

1.4.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	TP14 - Rodenticide Grains (baits, used as supplied) containing the active substance chlorophacinone are used in and around buildings, open areas and waste dumps. Grain products containing chlorophacinone are not used in sewers. Products can be supplied with sachets (professional and amateur) and without sachets (professional only).
Target organisms:	I.1.1.1 Brown rat: *Rattus norvegicus* I.1.1.2 Roof rat, House rat: *Rattus rattus* I.1.1.3 House mouse: *Mus musculus*
Category of users:	V1 Non professional / general public V.2 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:	VI.2 Covered application VI.2.1 in bait stations VI.2.2 other covering **1) For use in and around buildings.** The product is typically used in response to an infestation. Firstly, the size and extent of the infestation is determined by placing bait points containing bait only and observing the locations and amounts where bait is consumed (assume a rat consumes 25 g bait per day and a mouse 3.5 g per day). This is known as a pre-treatment baiting census. Also the target organism is identified. A pre-baiting census is less likely to be conducted by non-professionals (amateur) conducting small control campaigns indoors and more likely to be conducted by professionals conducting large scale control campaigns in and around farms and industrial areas. The purpose of the baiting census is to control the deployment of rodenticides in higher risk

	situations. The second phase involves replacing the bait with the rodenticide product. Depending on the infestation, over the area identified, the product is deployed in bait points containing up to 200 g every 4 to 5 m for rat infestations (or up to 50 g every 1 to 1.5 m for mice infestations). The bait points are visited on a regular basis (for example 1, 3, 7, 14, 21 days) and any consumed or spoilt rodenticide is replenished or replaced. Once the consumption of rodenticide has diminished sufficiently the second phase is deemed complete and any rodenticide not consumed is collected for disposal. A third phase can be conducted where bait points are again deployed with bait to determine the size of the population after the treatment. During the visits to bait points, any dead rodents visible are collected for disposal. **2) For use in open areas (by professional only) :** A pre-treatment baiting census is not always conducted. Product is deployed in burrows, up to 100 g per burrow and quantities can be double if consumption is complete. After the control campaign any rodenticide not consumed is collected for disposal. During the visits to the treated areas, any dead rodents visible are collected for disposal. **3) For use in waste dumps (by professional only) :** For treatments in waste dumps, the product is always used in sachets. The product is typically used in response to an infestation. Firstly, the size and extent of the infestation is determined by placing bait points containing bait only and observing the locations and amounts where bait is consumed (assume a rat consumes 25 g bait per day and a mouse 3.5 g per day). This is known as a pre-treatment baiting census. Also the target organism is identified. The second phase involves replacing the bait with the rodenticide product. Depending on the infestation, over the area identified, the product is deployed in bait points containing up to 200 g every 4 to 5 m for rat infestations (or up to 50 g every 1 to 1.5 m for mice infestations) around the perimeter of the waste

	dump. The bait points are visited on a regular basis (for example 1, 3, 7, 14, 21 days) and any consumed or spoilt rodenticide is replenished or replaced. Once the consumption of rodenticide has diminished sufficiently the second phase is deemed complete and any rodenticide not consumed is collected for disposal. A third phase can be conducted where bait points are again deployed with bait to determine the size of the population after the treatment. During the visits to bait points, any dead rodents visible are collected for disposal. The products are essentially little more than a food source (bait) and are a means to deliver the active substance to the target populations. As such the amounts of product used depend on the estimated size and extent of the target population (sufficient bait is used to ensure adequate uptake for each target rodent) rather than the product type. As such baits are used in similar ways. One of the factors affecting the uptake of a product is its attractiveness compared to other available food sources at a given location. The patterns of actual use of the products are not prescriptive and the usage patterns we have attempted to describe are considered to be realistic worst-cases in terms of amounts used. For smaller target populations less product will be used.
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	no
Proposed Label:	To be used against domestic rodents, *Rattus novegicus* (brown rat), *Rattus rattus* (black rats) and mice (*Mus musculus* spp.). Rat : up to 200 g every 4 to 5 meters, up to 100 g per burrow and quantities can be double if consumption is complete Mice : up to 50 g every 1 to 1.5 meters
Use Restrictions:	There are no specific use related restrictions.

1.4.3 Information on active substance(s)[1]

Active substance chemical name:	Chlorophacinone
CAS No:	3691-35-8
EC No:	223-003-0
Purity (minimum, g/kg or g/l):	> 97.8% w/w
Inclusion directive:	2009-99-CE
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(s) used in the biocidal product:	
Company Name:	LiphaTech S.A.S.
Address:	Chemie Park Trostberg, Dr Albert Frank strasse 32
City:	Trostberg
Postal Code:	83308
Country:	Germany
Telephone:	+33 5 53 69 81 90,
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E-mail address:	billeretm@desangosse.com

1.4.4 Information on the substance(s) of concern[2]

There is no substance of concern.

1.5 Documentation

1.5.1 Data submitted in relation to product application

Identity, physico-chemical and analytical method data

Physico-chemical properties studies and analytical methods on the biocidal product CAID GRAIN'TECH LR0191_02 and on another product CAID APPATS formulation R191 were provided by LIPHATECH.

[1] Please insert additional columns as necessary
[2] Please insert additional columns as necessary

Efficacy data

The following efficacy studies were submitted:

- Efficacy and palatability laboratory study – CAID GRAIN'TECH 3 month-aged bait with 0.005% chlorophacinone, brown rats (*Rattus norvegicus*);
- Efficacy and palatability laboratory study – CAID GRAIN'TECH with 0.005% chlorophacinone, brown rats (*Rattus norvegicus*);
- Efficacy and palatability laboratory study – CAID GRAN'TECH fresh bait with 0.005% chlorophacinone, house mice (*Mus musculus*);
- Efficacy and palatability laboratory study – CAID GRAIN'TECH 42 month-aged bait with 0.005% chlorophacinone, brown rats (*Rattus norvegicus*);
- Bait choice test – CAID BLOCK 20 month-aged bait with 0.005% chlorophacinone, black rats (*Rattus rattus*);
- Palatability laboratory study of placebo blocks containing two different concentrations of a bittering agent on brown rats (*Rattus norvegicus*);
- Palatability laboratory study of placebo blocks with two different kinds of packaging on brown rats (*Rattus norvegicus*).

Excepted for one efficacy study (on *R. rattus*), all studies have been realised with the product CAID GRAIN'TECH. As block bait form is less palatable than grain bait, a read-across is acceptable.

Toxicology, residue and ecotoxicology

No new human and environnment exposure studies have been submitted for the biocidal product authorisation

1.5.2 Access to documentation

No letter of access is needed as data belongs to the same applicant and the same origin of active substance used for the annex I inclusion.

2 SUMMMRY OF THE PRODUCT ASSESSMENT

CAID GRAIN'TECH containing 0.005% chlorophacinone is intended to be used in and around buildings, open areas and waste dumps against mice and rats. The product is supplied in sachets or loose grains for professional and non professional.
The applicant claim is summarized in annex 0.

The uses related to the open areas exclude golf courses, national parks, and islands, considered as not agricultural areas recovering from the pesticide regulation.

The product is to be used in tamper-resistant bait boxes, covered bait stations or in borrows.

Tamper-resistant bait boxes" are meant to be tamper-resistant devices, that prevent the access to the baits for children and non-target animals, and that protect the baits from bad weather.

Covered bait stations" are meant to be devices with the same level of security for the human beings and the environment than the security provided by tamper-resistant bait boxes, fastened to prevent any removal, made in order to avoid direct contact of the bait with the environment. This device must be designed to keep baits out of reach of the general public and non-target animals, and to protect the bait from bad weather

It is considered that professional users only (on the contrary to the general public) are able to design such covered bait stations.

2.1 Identity related issues

The source of the active substance used in the product CAID GRAIN' TECH is the same as the source used for the annex I inclusion.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

The proposed classification of active ingredient on annex I is the following:

Classification - Directive 67/548/EEC	
T+ ; R27/28	Very toxic in contact with skin and if swallowed.
T ; R23	Toxic by inhalation.
T : R48/24/25	Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed.
N ; R50/53	R50/53 : Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
No specific concentration limit available	

Classification - Regulation (EC) 1272/2008	
Acute Tox.Cat 1	H310: fatal if contact with skin
Acute Tox. Cat 2	H300 : fatal if swallowed
Acute tox. Cat 3	H331: toxic if inhaled

STOT RE Cat 1	H372: Causes damage to organs (state all organs affected if known) through prolonged or repeated exposure
Aquatic Acute tox. cat 1	H400 : Very toxic to aquatic life
Aquatic chronic tox. cat 1	H410 : Very toxic to aquatic life with long lasting effects.
No specific concentration Limit available	

2.2.2 Classification of the biocidal product

The proposed classification of CAID GRAIN' TECH is the following

Classification - Directive 67/548/EEC	
Class of danger	none
R phrases	none
S phrases (proposed by the RMS)	none

Classification - Regulation (EC) 1272/2008	
Hazard statement	none
Precautionary statements (proposed by the RMS)	none

2.2.3 Labelling of the biocidal product

The labelling according to Directive 1999/45/EC and Regulation (EC) 1272/2008 is the following

Symbols:	
Indications of danger:	None
Risk phrases:	None
Safety phrases:	None

Pictograms:	None
Signal words:	None
Hazard statements:	None

2.2.4 Packaging of the biocidal product

The packaging of the biocidal product as deposited by the notifier is:

For professional:

CAID GRAIN'TECH is supplied in sachet or loose.

Polyprolylene (PP) or polyethylene (PE), opaque or transparent sachets (20-100 g for rats and 20-50 g for mice) are packed in:
- Opaque metal box (500 g-1kg) ;
- PE or PP opaque lockable pouch (500 g-20 kg) ;
- PP opaque bucket (500 g-25 kg) ;
- Opaque cardboard carton (500 g-25 kg) ;
- PE or PP opaque container (500 g-4 kg) ;
- Opaque paper laminate bag (500g-25 kg).

Loose baits are packed in:
- -PE or PP opaque lockable pouch (500 g-20 kg) ;
- PP opaque bucket (500 g-25 kg) ;PE bag in opaque cardboard carton (500 g-25kg) ;
- PE or PP opaque container (500 g-4kg) ;
- Opaque paper laminate bag (500 g-25kg).

For non professional:

CAID GRAIN'TECH is supplied in sachet or loose.

PP or PE, opaque or transparent sachets (20-100g for rats and 20-50g for mice) are packed in:
- Opaque metal box (40 g-1kg) ;
- PE or PP opaque lockable pouch (40 g-4 kg) ;
- PP opaque bucket (40 g-4 kg) ;
- Opaque cardboard carton (40 g-4 kg) ;
- PE or PP opaque container (40 g-4kg).

Loose baits are packed in:
- PE or PP opaque lockable pouch (40 g-4 kg) ;
- PP opaque bucket (40 g-4kg) ;PE bag in opaque cardboard carton (40 g-4 kg) ;
- PE or PP opaque container (40 g-4 kg).

2.3 Physico/chemical properties and analytical methods

2.3.1 Active ingredient

2.3.1.1 Identity, origin of active ingredient

The source of the active substance used in the product CAID GRAIN' TECH is the same as the source used for the annex I inclusion.

2.3.1.2 Physico-chemical properties and analytical methods for determination of active ingredient and impurities in the technical active ingredient

Physical and chemical properties of the active substance and analytical methods for determination of active ingredient and impurities in the technical active substance have already been evaluated at EU level and are presented in the CAR (26 June 2009) of the active substance Chlorophacinone. The notifier of the product CAID GRAIN'TECH is the applicant that supported the annex I inclusion dossier of the active substance.

2.3.2 Biocidal product

2.3.2.1 Identity and composition of the biocidal product,

The biocidal product is not the same as the one assessed for the inclusion of the active substance in annex I of directive 98/8/EC.

Trade name: CAID GRAIN'TECH.

Code number: *CLOBL0,0050_05F_LR0191_02.*

The composition of the product is confidential and is presented in a confidential annex. There is no substance of concern.

2.3.2.2 Physico-chemical properties

Some studies have been performed on an other product CAID APPATS (formulation R191), results from these studies could be extrapolated to the product CAID GRAIN'TECH, formulation LR0191_02 on a case by case basis. When the read-across is accepted, it is indicated in the table. Otherwise new studies have been submitted and have been listed below.

(Sub)Section (Annex point)		Method	Purity/specifications	Results	Reference
B3.1	**Appearance (IIB, III 3.1)**				
	Physical state and nature	Visual	Formulation LR0191_02 Batch 8770 51.28mg/kg Chlorophacinone	Homogene wheat grains	Caruel, H., (2007a) IIIB 3.1.1-01 Amendment CLO0701E
	Colour	Visual	Formulation LR0191_02 Batch 8770 51.28mg/kg Chlorophacinone	Red	Caruel, H., (2007a) IIIB 3.1.2-01 Amendment CLO0701E
	Odour	Human smell	Formulation LR0191_02 Batch 8770 51.28mg/kg Chlorophacinone	Cereal odour	Caruel, H., (2007a) IIIB 3.1.3-01 Amendment CLO0701E
B3.2	**Explosive properties (IIB, III 3.2)**	Theoretical assessment	Formulation R191	Non explosive Read across acceptable for the product CAID GRAIN'TECH LR0191_02. See comment below the table.	Lindemann, M. (2004a) IIIB 3.2-01
B3.3	**Oxidising properties (IIB, III 3.3)**	Theoretical assessment	Formulation R191	No oxidising properties Read across acceptable for the product CAID GRAIN'TECH LR0191_02. See comment below the table.	Lindemann, M. (2004b) IIIB 3.3-01
B3.4	**Flash-point and other indications of flammability or spontaneous ignition (IIB, III 3.4)**				
	Flash point	Not required as the product is a solid			

	Auto-flammability	EC A.16	Formulation R191 Batch: E8641 55.7 mg/kg Chlorophacinone	Self ignition temperature : 387°C An exothermic reaction occurs at 240 °C, this reaction is very slow (364.5 min) and the maximal temperature reached by the test item is 481.4°C. This reaction is not considered as a self-ignition temprature. The test item is not auto-flammable at ambient temperature. Read across acceptable for the product CAID GRAIN'TECH FR0191_02. See comment below the table.	Lindemann, M. (2004c) IIIB 3.4-01
	Other indications of flammability:	EC A.10	Formulation R191 Batch: E8641 55.7 mg/kg Chlorophacinone	Not highly flammable Read across acceptable for the product CAID GRAIN'TECH FR0191_02. See comment below the table.	Lindemann, M. (2004d) IIIB 3.4-02
B3.5	**Acidity / alkalinity (IIB, III 3.5)**				
	pH value	CIPAC MT75	Formulation LR0191_02 Batch F584 54.53mg/kg Chlorophacinone	6.96 at 25 °C	Caruel, H., (2012) IIIB 3.7-04v2
B3.6	**Relative density (IIB, III 3.6)**				
	Relative density	CIPAC MT186	Formulation LR0191_02 Batch F2911 52.55mg/kg Chlorophacinone	Pour density : 0.766 g/mL Tap density : 0.809 g/mL	Ferron, N. (2012) IIIB 3.6-02
B3.7	**Storage stability-stability and shelf life (IIB, III 3.7)**				

	Stability after accelerated storage for 14 days at 54 ℃	14 days, 54℃ GIFAP Technical Monograph No.17	Formulation LR0191_02 Batch F584 53.19mg/kg Chlorophacinone	Aspect of the test item, packaging and pH of 1% water dispersion did not change significantly after storage. Difference of content of the active substance: +7.9% deviation from T=0 after the storage for 14 days at 54℃. See comment below the table	Caruel, H. (2007b) IIIB 3.7-01 Amendment CLO0702E
	Shelf life following storage at ambient temperature	60 months at 25℃ storage stability study	Formulation LR0191_02 Batch F584 54.53mg/kg Chlorophacinone	Aspect of the test item, packaging and pH of 1% water dispersion did not change significantly after storage Difference of content of the active substance: -8% deviation from T=0 after the storage for 60 months at 25℃. (between 18 and 27.6℃) See comment below the table.	Caruel, H., (2012) IIIB 3.7-04v2
	Reactivity towards container material	60 months at 25℃ storage stability study Visual inspections	Formulation LR0191_02 Batch F584 54.53mg/kg Chlorophacinone White PP box	No alteration observed during the 60 months	Caruel, H., (2012) IIIB 3.7-04v2

		14 days, 54℃ Visual inspections	Formulation LR0191_02 Batch F2911 52.55mg/kg Chlorophacinone PE sachet (~20g) PP sachet (~20g) Laminate paper sachet (~20g)	After 14 days at 54 ℃, no change of colour, no alteration on the surface and no damage on the sachet were observed. No analytical results have been provided. See comment below	Deslux, R., (2012) IIIB 3.7-05
B3.8	**Technical characteristics (IIB, III 3.8)**				
	Wettability	Not required as the product is a ready to use grain bait			
	Persistent foaming	Not required as the product is a ready to use grain bait			
	Suspensibility	Not required as the product is a ready to use grain bait			
	Spontaneity of dispersion	Not required as the product is a ready to use grain bait			
	Dilution stability	Not required as the product is a ready to use grain bait			
	Dry sieve test	See particle size distribution			
	Wet sieve test	Not required as the product is a ready to use grain bait			
	Dust content	CIPAC MT171	Formulation LR0191_02 Batch F2911 52.55mg/kg Chlorophacinone	Nearly dust free	Ferron, N. (2012) IIIB 3.8-04
	Attrition resistance of granules	CIPAC MT178	Formulation LR0191_02 Batch F2911 52.55mg/kg Chlorophacinone	100%	Ferron, N. (2012) IIIB 3.8-04

	Emulsifiability / Emulsion stability / Re-emulsifiability	Not required as the product is a ready to use grain bait			
	Stability of dilute emulsions	Not required as the product is a ready to use grain bait			
	Flowability	CIPAC MT172	Formulation LR0191_02 Batch F2911 52.55mg/kg Chlorophacinone	The flowability was not spontaneous through the 5-mm sieve. The mean percentage of test item retained on the 5-mm sieve after 5 liftings was: 0% w/w.	Ferron, N. (2012) IIIB 3.8-04
	Pourability (including rinsed residue)	Not required as the product is a ready to use grain bait			
B3.9	**Compatibility with other products (IIB, III 3.9)**	This ready to use grain preparation is not intended to be used or mixed with other products.			
B3.10	**Surface tension and viscosity (-)**				
	Surface tension	Not required as the product is a ready to use grain bait			
	Viscosity	Not required as the product is a ready to use grain bait			
B 3.11	**Particle size distribution (-)**	CIPAC MT59.4	Formulation LR0191_02 Batch F2911 52.55mg/kg Chlorophacinone	87.5 % of the particles are bigger than 2.8mm and 12.1% are between 2 and 2.8 mm.	Ferron, N. (2012) IIIB 3.11

Explosive and oxidising properties, flammability and auto-flammability:

The read across is acceptable for these properties. The difference in composition between the product CAID GRAIN'TECH (LR0191_02) and the product CAID APPATS (formulation R191) tested is 1%.
The common and new formulants have no oxidising and no explosive properties and are not flammable.

The product CAID GRAIN'TECH (LR0191_02) is considered to have no oxidising and no explosive properties and to be neither highly flammable nor auto-flammable at ambient temperature.

Storage stability:

60 months at 25℃ storage stability study:

After five years the active substance content decreases of 8%. However intermediate result at 2 years shows a decrease of 12.6% of the active substance content. The accepted variation is 10% according to the Monography 17. The aspect of the test item during the storage has not changed. The pH was measured during and after the five years and no significant changes were observed. Moreover efficacy study performed after 42 months at ambient temperature shows that product is effective. So FR considers that the product is stable during 3.5 years.

The active substance content during the 60 months fluctuates between – 0.4% and – 12.6%.

After 3 months	After 6 months	After 9 months	After 12 months
-7.3%	-5.8%	-6.0%	-5.3%
After 24 months	After 36 months	After 48 months	After 60 months
-12.6%	-4.1%	-0.4%	-8.1%

25% is the accepted variation of the specification in the product according to the FAO manual[3] (§4.3.2)). The variation of active substance content may be due to the heterogeneity of grains within batches (grains from a batch may have different contents of active substance). Therefore the sampling should be adapted to overcome this heterogeneity. Moreover possibility of adsorption of the active substance on the matrix has not been investigated.

FR CA[4] considers that the shelf life of the product CAID GRAIN'TECH is 3.5 years. If the notifier wants to claim a shelf life of five years, efficacy study after five years storage will be required.

- **14 days at 54 ℃ study:**

The active substance content after 14 days at 54℃ is +7.9%. The difference in active substance content is higher than 5% which is the accepted variation according to the FAO manual[5] (§4.6.2). Aspect of the test item during the storage has not changed and no significant changes were observed for pH measures after storage 14 days at 54 ℃. Moreover chlorophacinone is thermically stable (melting point à 140 ℃ and decomposition st arted at 250 ℃). The same heterogeneity and adsorption questions arise. The effect of temperature should be demonstrated by the submission of

[3] Manual on development and use of FAO and WHO specifications for pesticides ; November 2010 - second revision of the First Edition.
[4] FR CA : France competent authority .
[5] Manual on development and use of FAO and WHO specifications for pesticides ; November 2010 - second revision of the First Edition.

a new accelerated storage stability study (14 days at 54 ℃ or at a lower temperature) with acceptable results.

The compatibility of the product CAID GRAIN'TECH with the PE, PP and paper laminate sachet of 20 g has been demonstrated which covers all the claimed packagings.

The effect of light has not been provided and FR recommends to store away from light due to the sensitivity of the active substance to light. All the claimed packagings are opaque.

Data requirements

An accelerated storage stability study (14 days at 54℃ or at a lower temperature) is required with CIPAC MT46.

2.3.2.3 Analytical method for determining the active substance and relevant component in the biocidal product

Sample	Test substance	Analytical method	Linearity	Fortification range/ number of measurements	Specificity	Recovery rate (%)			Repeatability	reference
						range	Mean	St dev.		
CAID GRAIN'TECH (formulation LR0191_02)	Chlorophacinone	HPLC-UV (DAD) 286 nm	0.5-2.1 mg/100 mL, 6 concentrations in duplicate r^2=0.9983	Fortification levels : 50 mg/kg, 3 replicates in duplicate	No demonstrated	At 50mg/kg : 99.4 - 102.1%	At 50mg/kg: 100.6 %	At 50mg/kg: 1.4mg/kg	Not demonstrated	Caruel, H. (2007) Amendment CLO0702D

The provided analytical method is not fully validated. Specificity and repeatability have not been demonstrated.

These validation data are required in post registration to fully validate the method.

2.3.2.4 Analytical methods for determining relevant components and/or residues in different matrices

The analytical methods for determination of residues of active substance in different matrices (soil, air, drinking and surface water, blood and liver) provided in the CAR of the active substance are presented in annex I of this document. An analytical method for determination of residues in food and feedstuff is not required as there is no dietary exposure.

2.4 Risk assessment for physico-chemical properties

CAID GRAIN'TECH is a grain ready-to-use rodenticide. It is not highly flammable, not auto-flammable at ambient temperature, not explosive and does not have oxidizing properties.

Results of the accelerated storage study are not acceptable and a new study has to be provided in post registration. The product CAID GRAIN'TECH is stable 3.5 years at ambient temperature and compatible with PE sachet, PP sachet and paper laminate sachet of 20 g.

Risk mitigation measures linked to assessment of physico-chemical properties.

- Store away from light

Required information linked to assessment of physico-chemical properties

- An accelerated storage stability study (14 days at 54℃ or at a lower temperature) with CIPAC MT46 is required in post registration.

- Further validation data of the analytical method for the determination of chlorophacinone in the product CAID GRAIN'TECH are required in post registration (specificity and repeatability).

2.5 Effectiveness against target organisms

2.5.1 Function

MG 03: Pest Control
Product Type 14: Rodenticide

2.5.2 Organisms to be controlled and products, organisms or objects to be protected

According to the uses claimed by the applicant, CAID GRAIN'TECH is intended to be used to control rodents. The target organisms to be controlled are brown rats (*Rattus norvegicus*), black rats (*Rattus rattus*) and house mice (*Mus musculus*).

The application rates recommended and uses claimed by the applicant are the following (see also annex 0):

Target organisms	Area of use	Dosage claimed	Time delay of the action of the product	Frequency and method of controls	Distance between 2 bait points, for high and low infestation	Methods of application of the bait
Professional user						
Rats	In and around buildings	Up to 200 g / bait point	4 to 6 days	High infestation : 3 days after first application then every week or 15 days Low infestation: 1 week after first application then every week or 15 days If complete consumption, repeat the treatment.	4-5 meters 8-10 meters	Manual application in bait stations, bait points or in burrow
Mice		Up to 100 g / bait point			1-1.5 meters 2-3 meters	
Rats	Open areas	Up to 200 g / bait point	4 to 6 days	High infestation : 3 days after first application then every month Low infestation: 1 week after first application then every month If complete consumption, repeat the treatment.	3-5 meters 10-15 meters	Manual application in bait stations, bait points or in burrow
Mice		Up to 100 g / bait point			3-5 meters 10-15 meters	
Rats	Waste dumps	Up to 200 g / bait point	4 to 6 days	Application every 2 to 3 month.	3-5 meters 10-15 meters	

Non professional user						
Rats	In and around buildings	Up to 200 g / bait point	4 to 6 days	High infestation : 3 days after first application then every week or 15 days Low infestation: 1 week after first application then every week or 15 days If complete consumption, repeat the treatment.	4-5 meters 8-10 meters	Manual application in bait stations, bait points or in burrow
Mice		Up to 100 g / bait point			1-1.5 meters 2-3 meters	

2.5.3 Effects on target organisms and efficacy

Anticoagulants Rodenticides disrupt the blood-cutting mechanisms. Signs of poisoning in rodents are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. After feeding on bait containing the active substance for 1 - 5 days the animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop, the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. As the active substance has a long acting action, death will usually occur within 4 to 17 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.

- Efficacy on house mice (*Mus musculus*)

Efficacy and choice feeding test was conducted with fresh baits CAID GRAIN'TECH on mice (sensitive strain to warfarin) and results are presented in the dossier. The study shows that the product is very palatable (average treated bait intake of 93 % of the total food consumption) and effective (96 % of mortality between 5 to 11 days). The study guideline corresponds to the recommendations of the TNsG on product evaluation annex PT14: consumption > 20 % and mortality rate ≥ 90 %. Thus, field tests on mice are not required.

- Efficacy on black rats (*Rattus rattus*)

Efficacy and choice feeding test was conducted with 20 month-aged baits CAID BLOCK on black rats (sensitive strain to warfarin). The results are presented in the dossier: the study shows that the product is palatable (average treated bait intake of 51 % of the total consumption) and effective (89 % of mortality between 7 to 14 days). As the block bait form is less palatable than the grain bait one then a read-across is acceptable.
The guideline study corresponds to the recommendations of the TNsG on product evaluation annex PT14: consumption > 20 % and mortality rate ≥ 90 %. Thus, field tests on black rats are not required.

- Efficacy on brown rats (*Rattus norvegicus*)

Efficacy and choice feeding tests were conducted with fresh baits CAID GRAIN'TECH on brown rats (sensitive strain to warfarin). The results are presented in the dossier.
The studies show that the product is palatable (average treated bait intake respectively of 52 % and 44 % of the total food consumption) and effective (100 % of mortality between 5 to 15 days and 89 % of mortality between 4 and 17 days).

Another study has been performed with 42 month-aged baits CAID GRAIN'TECH on brown rats (sensitive strain to warfarin). The results are presented in the dossier: the study shows that the product is palatable (average treated bait intake of 66 %) and effective (100 % of mortality between 9 and 17 days).

The guideline studies correspond to the recommendations of the TNsG on product evaluation annex PT14: consumption > 20 % and mortality rate ≥ 90 %. Thus, field tests on brown rats are not required.

All efficacy studies results are presented in annex 9.

According to the areas claimed by the applicant, the product is applied in bait stations, bait boxes or burrows, by professional (in and around buildings, open areas, and waste dumps) and non-professional users (in and around buildings only) in discrete locations within the infested area. Distances between each bait point, so as the number and timings of application and the amount of product depends of several factors: the treatment site, the size and severity of the infestation.

On the basis of the efficacy data submitted, the level of efficacy of the product CAID GRAIN'TECH for the intended uses presented in the table below are validated.

Validated efficacy data

Target organisms	Area of use	Dosage claimed	Time delay of the action of the product	Frequency and method of controls	Distance between 2 bait points, for high and low infestation
Professional users					
Rats	In and around buildings	200 g / bait point	4 to 17 days	Inspect and resupply the bait points, 3 days after application then once a week as long as the bait is consumed.	4-5 meters 8-10 meters
Mice		100 g / bait point			1-1.5 meters 2-3 meters
Rats	Open areas	200 g / bait point			3-5 meters 10-15 meters
Mice		100 g / bait point			3-5 meters 10-15 meters
Rats	Waste dumps	200 g / bait point		Inspect and resupply the bait points, 1 week after application then once a month as long as the bait is consumed.	3-5 meters 10-15 meters
Non professional users					
Rats	In and around buildings	200 g / bait point	4 to 17 days	Inspect and resupply the bait points, 3 days after application then once a week as long as the bait is consumed.	4-5 meters 8-10 meters
Mice		100 g / bait point			1-1.5 meters 2-3 meters

2.5.4 Mode of action including time delay

Chlorophacinone acts as a vitamin K1 antagonist. It interferes with the regeneration of prothrombin disturbing the normal blood clotting mechanisms and increasing tendency to bleed. The main site of its action is the liver, where several of the blood coagulation precursors under vitamin K dependent post translation processing take place before they are converted into the respective procoagulant zymogens. Chlorophacinone acts as an inhibitor of K1 epoxide reductase, preventing the regeneration of vitamin K and preventing activation of clotting factors.

2.5.5 Occurrence of resistance

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%. Some degree of resistance to 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 anti-coagulants (Greaves et al., 1982[6]; Lund, 1984[7]; Pelz et al. 1995[8]). The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 (Greaves and Cullen-Ayres 1988[9]). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. Greaves et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of reports in UK of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products are increasingly being attributed to baiting problems rather than physiological resistance (Greaves and Cullen Ayres, 1988; Quy et al. 1992a,b[10]).

Recent studies carried out in different European countries, in the UK more particularly (Kerins *et al*, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats (*Rattus norvegicus*) populations to coumafene. Moreover, a recent publication (Baer *et al.*, 2012) has demonstrated that the majority (91%) of warfarin resistant rats trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadionone (Grandemange *et al.*, 2009). More recently, the same mutation was also found in the UK (Prescott *et al.*, 2011) where applications of bromadiolone had been unsuccessful. Difenacoum

[6] Greaves J. H.; Shepherd D. S.; Gill, J. E. (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *Annals of Applied Biology* 100, 581–587.
[7] LUND, M. (1984): Resistance to the second generation anticoagulant rodenticides. *In Proceedings of 11th vertebrate pest conference*, Sacramento, Ca. March 6-8, 1984: 89-94.
[8] Pelz H-J, Ha¨nisch D, Lauenstein G (1995) Resistance to anticoagulant rodenticides in Germany and future strategies to control *Rattus norvegicus. Pestic Sci* 43, 61–67
[9] Greaves J. H.; Cullen-Ayres P. B. (1988): Genetics of difenacoum resistance in the rat. In: J. W. Suttie (Ed.), Current advances in vitamin K research, Elsevier, N.Y., 381–388.
[10] Quy R.J., Shepherd D.S., Inglis I.R. (1992): Bait avoidance and effectiveness of anticoagulant rodenticides against warfarin- and difenacoum-resistant populations of Norway rats (Rattus norvegicus). *Crop Protection*, Volume 11, Issue 1, February 1992, Pages 14-20

is also thought to be partially resisted by rats which carry Y139F. So, resistance to second generation anticoagulant rodenticides should not be minimized.

Only an exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first-generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program "*impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators*").

Resistance management strategies

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance.

CropLife International has published a strategy for resistant management of rodenticides (RRAC 2003). The habitat management is addressed in the strategy in addition to chemical control. The access of rodents should be restricted by physical barriers and no food should be available for rodents. Rotation between different anticoagulants is not a reliable means of managing the anticoagulant resistance, as all anticoagulants have the same mode of action and the nature of resistance is also similar. The resistant individuals can be identified by conducting a blood clotting response (BCR) test (Gill et al. 1993, RRAC 2003). The problem with the BCR test is that it has proven difficult to standardise and it produces both false positives and negatives (Pelz et al. 2005). In order to follow the occurrence and spread of difenacoum resistance, wild rats should be continuously monitored for resistance in the rodent controlled area. The recommendations of CropLife International are quoted below.

To avoid the development of resistance in susceptible rodent populations:

- When anticoagulant rodenticide is used, ensure that all baiting points are inspected weekly and old bait replaced where necessary.
- Undertake treatment according to the label until the infestation is completely cleared.
- On completion of the treatment remove all unused baits.
- Do not use anticoagulant rodenticides as permanent baits routinely. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas.
- Monitoring of rodent activity should be undertaken using visual survey, through the use of non-toxic placebo monitors or by other effective means.
- Record details of treatment.
- Where rodent activity persists due to problems other than resistance, use alternative baits or baiting strategies, extend the baiting program or apply alternative control techniques to eliminate the residual infestation (acute or sub-acute rodenticides, gassing or trapping).
- Ensure that complete elimination of the infestation is achieved, In case of suspected resistance, testing for genetic resistance have to be performed by molecular biological methods.
- As appropriate during the rodenticide treatment, apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, remove harbourage and proof susceptible areas against rodent access).

Treatment of rodent infestations containing resistant individuals:

- Where rodent infestations containing resistant individuals are identified, immediately use an alternative anticoagulant of higher potency. If in doubt, seek expert advice on the local circumstances.
- Alternatively use an acute or sub-acute but non-anticoagulant rodenticide.
- In both cases it is essential that complete elimination of the rodent population is achieved. Where residual activity is identified apply intensive trapping to eliminate remaining rodents. Gassing or fumigation may be useful in specific situations.
- Apply thorough Integrated Pest Management procedures (environmental hygiene, proofing and exclusion).
- Do not use anticoagulant rodenticides as permanent baits as routine. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high risk areas.
- Record details of treatment.

Application of area or grain rodent control to eliminate resistance:

- Where individual infestations are found to be resistant or contain resistant individuals it is possible that the resistance extends further to neighbouring properties.
- Where there are indications that resistance may be more extensive than a single infestation, apply area or grain control rodent programmes.
- The area under such management should extend at least to the boundaries of the area known resistance and ideally beyond.
- These programmes must be effectively coordinated and should encompass the procedures identified above.

The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

2.5.6 Evaluation of the Label Claims

French Competent Authorities (FR CA) assessed that CAID GRAIN'TECH has shown a sufficient efficacy for the control of mice and rats for use in and around buildings, in open areas and in waste dumps for professional users and only in and around buildings for non professional users.

The application rates validated are presented in the annex 2:

In addition to the bulk packaging, CAID GRAIN'TECH is also supplied in sachets of different amounts. The applicant has to adapt the amount per sachet to the efficient doses. The amount of bait per bait station must not exceed the recommended application rates.

In order to reflect the efficacy data of the product labels has to be revised as following:

- Inspections of bait points have to be made three days after the first application then weekly for the uses in and around buildings, and open areas; one week after the first application then every month for the uses in waste dump.
- The time delay of the product's action should be added on the basis of efficacy tests (4 to 17 days).
- It should be precised that the shelf life of the product is 42 months.
- Golf courses are excluded from open areas

Because of cross-resistances occurrence to second-generation anticoagulants, the product label has to contain information on resistance management for rodenticides (see *Specific use restriction and issues accounted for product labelling* below).

Conclusion for efficacy assessment

The product CAID GRAIN'TECH has shown a sufficient efficacy for the control of mice (*Mus musculus*) and rats (*Rattus norvegicus* and *Rattus rattus*). Nevertheless, a monitoring of the resistance phenomenon of rodent populations toward the active substance chlorophacinone and resistant strategies management must be put in place. The collected information must be sent every 2 years to Anses within the framework of a post-authorization monitoring.

Conditions of use linked to efficacy assessment

For professional users:

- Adapt the number of bait station to the infestation level.
- Adapt the quantity of bait per bait station to the validated effective dose.
- Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed for the uses in and around the building, and open areas; one month after application then once a month for the uses in waste dumps.
- Remove all bait stations at the end of the treatment.
- The label has to respect the recommended conditions of use and the biocidal products labelling guide[11].
- The amount of bait per bait station and distances between bait stations must be respected. Products have always to be used in accordance with the label.
- To avoid resistance and because of cross-resistances occurrence to second-generation anticoagulants:
    - The product label has to contain information on resistance management for rodenticides
    - The treatment has to be alternated with other kinds of active substances having different modes of action.
    - The level of efficacy have to be monitored (periodic check), and the case of reduced efficacy has to be investigated for possible evidence of resistance.

[11] Guide à l'intention des responsables de la mise sur le marché des produits biocides. Lignes directrices sur l'étiquetage des produits biocides mis sur le marché. Version du 28 août 2007.

- Resistant management strategies have to be developed, and chlorophacinone must not be used in an area where resistance to this substance is suspected or established.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures.
- The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
- do not use the product in areas where resistance is suspected or established.

For non professional users:

- Adapt the number of bait station to the infestation level.
- Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.
- The label has to respect the recommended conditions of use and the biocidal products labelling guide[12].
- The amount of bait per bait station and distances between bait stations must be respected. Products have always to be used in accordance with the label.
- To avoid resistance:
    - Adapt the quantity of bait per bait station to the validated effective dose.
    - The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Chlorophacinone is used as rodenticide (product type PT14 according to EU Biocidal Product Directive).

[12] Guide à l'intention des responsables de la mise sur le marché des produits biocides. Lignes directrices sur l'étiquetage des produits biocides mis sur le marché. Version du 28 août 2007.

The validated application rates and intended uses are the following:

Target organisms	Area of use	Dosage claimed	Time delay of the action of the product	Frequency and method of controls	Distance between 2 bait points, for high and low infestation
Professional users					
Rats	In and around buildings	200 g / bait point	4 to 17 days	Inspect and resupply the bait points, 3 days after application then once a week as long as the bait is consumed.	4-5 meters 8-10 meters
Mice		100 g / bait point			1-1.5 meters 2-3 meters
Rats	Open areas	200 g / bait point			3-5 meters 10-15 meters
Mice		100 g / bait point			3-5 meters 10-15 meters
Rats	Waste dumps	200 g / bait point		Inspect and resupply the bait points, 1 week after application then once a month as long as the bait is consumed.	3-5 meters 10-15 meters
Non professional users					
Rats	In and around buildings	200 g / bait point	4 to 17 days	Inspect and resupply the bait points, 3 days after application then once a week as long as the bait is consumed.	4-5 meters 8-10 meters
Mice		100 g / bait point			1-1.5 meters 2-3 meters

The efficacy of the product CAID GRAIN'TECH has been proved for the control of mice (*Mus musculus*), brown rats (*Rattus norvegicus*) and black rats (*Rattus rattus*) indoors and outdoors (in and around buildings, in open areas and in waste dump sites). The control of mice and rats is based on the principle of applying baits on infested areas with obvious tracking of faeces, and smears next to holes and harbourages.

The product is a ready-to-use grain bait with no dilution and or other substances added for application. The mode of application claimed by the applicant is manual applied by professional users and by non professional users in secured bait boxes, bait stations or burrows.

2.7 Risk assessment for human health

2.7.1 Assessment of exposure to humans

No new human exposure studies have been submitted.
In the dossier, Liphatech assessed the human exposure based on the studies of Chambers *et al.* and Snowdon and the Human Exposure Expert Group (HEEG) opinion on an Harmonised approach for the assessment of rodenticides (anticoagulants). However, contrary to use the 75th percentile over all at it is recommended in the HEEG opinion, Liphatech used the geometric mean.

For non professional users, the same studies and assumptions were used for the estimation of human exposure since the values available in the TNsG and User Guidance (Human exposure to biocidal products – TNsG June 2002 – version 1) are considered as unrealistic.

Additionally, the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMIII 2010 and the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011 were taken into account for the estimation of exposure for professionals and non professionals.

2.7.2 Hazard potential

2.7.2.1 Toxicology of the active substance

.
The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 „Toxicology and metabolism" must be taken into consideration.
The following corresponds to the summary of the derivation of the AELs from the Doc I of the final CAR of chlorophacinone:

"The derivation of an Acceptable Operator Exposure Level (AOEL) value for repeated use is based on the NOAEL established in a 90-day study in the rat (no dog study was performed). The NOAEL established in the rat study was 5 µg/kg/day. Nevertheless, the 5 µg/kg/day group was terminated at week 11 and coagulation (quick) time was not determined. Hence, there is some uncertainty about whether 5 µg/kg bw/day can be considered as NOEL on the basis of coagulation quick time (significant increases of the coagulation quick time were noted in 10 µg/kgbw/day males). Therefore, an application of an additional assessment factor may be considered appropriate. Furthermore, it is not sure that rat is the most sensitive species as in a dog (fed with vitamin K deficient diet) dogs were more sensitive than rats. An additional factor of 3 has been proposed for all anticoagulant

rodenticides. This could cover the above mentioned uncertainty. The standard factors of 10 for both inter and intraspecies were considered adequate. Therefore, based on the NOEL value of 0.005 mg/kg/day derived from the 11-week rat study and a total assessment factor of 300, an AOEL of 0.000017 mg/kg bw/day was calculated.

The acute AOEL for risk characterization was deduced from the lowest relevant NOAEL for maternal toxicity in teratogenicity studies. A value of NOAEL of 10 µg/kg bw/day on the basis of mortality in rabbit was adopted. Clinical signs of toxicity and necropsy pathology demonstrated that mortality in rats and rabbits was due to internal haemorrhage caused by the anticoagulant properties of the substance. Treatment-related clinical observations were limited to doses causing mortality prior to death. There were no treatment-related clinical signs of toxicity at lower doses. At scheduled necropsy, there were no treatment-related findings in surviving pregnant animals.
Due to the severity of the effects an extra assessment factor of 3 may be applied with a total assessment factor of 300.

Therefore, based on the NOEL value of 0.010 mg/kg/day derived from systemic toxicity in teratogenicity study in rabbits and a total assessment factor of 300, an AOEL of 0.000033 mg/kg bw/day was calculated."

2.7.2.2 Toxicology of the substance of concern

The biocidal product contains no substances of concern:
The basis for health assessment of the substance of concern is laid out in Annex 5 "Toxicology – biocidal product".

2.7.2.3 Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.
The basis for the health assessment of the biocidal product is laid out in Annex 6 "Toxicology – biocidal product".

New data:
Acute oral and dermal toxicity, skin and eye irritation and skin sensitisation studies have been provided on the product CAID GRAIN' TECH.

2.7.2.3.1 Acute Oral and dermal toxicity

No mortality, systemic or local effects were observed in these studies.
Based on the results, no classification is required for CAID GRAIN' TECH.

Route	Method Guideline	Species Strain Sex no/group	Dose levels duration of exposure	Value LD50/LC50	Remarks
Oral	EPA 81-1	Rat Sprague-Dawley 5 male/group 5 female/group	Single dose, 400 mg/mL suspension in distilled water at 12.5 mL/kg bw. Post exposure period, 21 days	Limit dose, 5000 mg/kg bw, resulted in no deaths. LD_{50} value is > 5000 mg/kg bw.	Limit dose, 5000 mg/kg bw, resulted in no deaths.
Dermal	EPA 81-2	Rabbit	Single dose equivalent to	Limit test:	No mortality or

		Hra: (NZW) SPF 5 males/group 5 female/group	2000 mg/kg bw, applied to 10% body surface for 24 hours	LD_{50} greater than 2000 mg/kg bw.	signs of toxicity.
Dermal	EPA 81-2	Rabbit New Zealand White 6 males/group 4 female/group	Single dose equivalent to 2000 mg/kg bw, applied to 10% body surface for 24 hours	LD_{50} greater than 2000 mg/kg bw.	No mortality or signs of toxicity.

2.7.2.3.2 Irritation and corrosivity

Based on the results of the irritation assays on rabbit's skin and eye, no classification is required for CAID GRAIN' TECH.

Skin irritation

Species	**Method**	**Average score 24, 48, 72 h**		**Reversibility yes/no**	**Result**
		Erythema	**Oedema**		
Rabbit	EPA 81-5	0.00	0.00	Not applicable (no effects observed)	Test material is considered to be a non-irritant.
Rabbit	EPA 81-5	0.00	0.00	Minor transient erythema present 1 h after dosing in two animals had resolved within 24 hrs	Test material is considered to be a non-irritant.

Eye irritation

Species	**Method**	**Average Score**				**Reversibility yes/no**	**Result**
		Cornea	**Iris**	**Conjunctiva**			
				Redness	**Chemosis**		
Rabbit	EPA 81-4	0.00	0.00	0.33	0.00	Yes. Conjunctival redness was the only change and had resolved within 72 h of treatment.	Test material not classification as an eye irritant.
Rabbit	EPA 81-4	0.00	0.00	0.72	0.00	Yes Iridial congestion, conjunctival redness and swelling present 1 h after treatment. Changes largely resolved within 24 hrs. Slight conjunctival redness persisted in several treated eyes after 72 hrs but had resolved by Day 7.	Test material not classification as an eye irritant.

2.7.2.3.3 Sensitisation

Based on the results of the Buehler test on guinea pig, no classification is required for CAID GRAIN' TECH.

Species	Method	Number of animals sensitized/total number of animals	Result
Guinea Pig	EPA 81.6	Controls: 10 males Test group: 10 males Positive controls: 4 males	Test material gave no evidence for inducing delayed contact hypersensitivity in a Buehler test and therefore is not classified as a sensitiser
Guinea Pig	EPA 81.6	5 males and 5 females in each of four test groups (test material, positive control and respective naïve controls)	Test material gave no evidence for inducing delayed contact hypersensitivity in a Buehler test and therefore is not classified as a sensitiser

Justification for non submission

- **Dermal absorption**

Liphatech proposed a dermal absorption of 1.7 % from the Assessment report on chlorophacinone, where the active substance is applied to human skin in the form of a cereal flour/aqueous slurry. This dermal absorption value was considered for the risk assessment of CAID GRAIN' TECH.

- **Acute inhalation toxicity**

The generation of inhalable particle is considered as negligible in particular when CAID GRAIN' TECH is supplied in sachet. Additionally, the vapor pressure of chlorophacinone is low (4.76×10^{-4} Pa at 23℃). Therefore, an acute toxicity test by i nhalation is not required.

Classification

The current harmonised classification of the active substance is the following:

Classification under directive 67/548/EEC	Classification under regulation (EC) 1272/2008
T+ R27/28 T R23-R48/24/25 No specific limit concentrations	Acute Tox 1 H310 Acute Tox 2 H300 Acute Tox 3 H331 STOT RE Cat 1 H372 No specific limit concentrations

Based on the results of the studies, the concentration of the active substance and of other components contained in the product and according to the above classification, CAID GRAIN' TECH is not classified.

2.7.2.4 Others studies

The product is not used with other biocidal products. Therefore, no additional study was conducted.

The product is a solid bait only used, in buildings, in secured bait points. Collecting unconsumed baits and dead rodents must be done every week during the treatment so in these recommended

conditions, no contamination is expected for feeding stuffs. Finally, according to the Assessment report on chlorophacinone, "*chlorophacinone baits should not be placed where food, feedingstuffs or drinking water could be contaminated*". Therefore, no data on residue was submitted.

2.7.3 Human exposure assessment

CAID GRAIN'TECH (PT14) is a ready-to-use rodenticide containing 0.005 % of chlorophacinone (pure: 978g/kg). Baits are packaged in bulk or in sachet for professional users.The baits are placed in bait stations (bait boxes or secured bait stations) out of reach of children and domestic animals.

2.7.3.1 Identification of main paths of human exposure towards active substance from its use in biocidal product

The potential for exposure to chlorophacinone grain baits is summarised in the table below:

Exposure path	Industrial use	Professional use	General public	*via* the environment
Inhalation	Not relevant	Potentially significant	Negligible	Negligible
Dermal	Not relevant	Potentially significant	Potentially significant	Negligible
Oral	Not relevant	Negligible	Negligible	Negligible

2.7.3.1.1 Exposure of professional users

CAID GRAIN' TECH is used for the control of rats and mice in and around buildings, in open areas and waste dumps, with the purpose of protecting human food and animal feedstuffs, and for human hygiene.

Inhalation exposure

Exposure by inhalation route is relevant **during the decanting** of the product supplied loose. Based on the CEFIC study and taking into account the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011, the air concentration is 9.62 mg product/m^3.
The following parameters were considered:

- duration of manipulation: 15 minutes per day for rats (3 minutes per decanting; 12.6 kg decanted in 3 kg buckets per day) and 9 minutes per day for mice (3 minutes per decanting; 3 decanting per day)
- Inhalation rate: 1.25 m^3/hour
- Inhalation absorption: 100 %
- Active substance in product: 0.005 %
- Body weight: 60 kg

Based on these assumptions, the systemic concentration of chlorophacinone is $8.3x10^{-6}$ mg/kg bw/day for the control of rats and $6.9x10^{-6}$ mg/kg bw/day for the control of mice.

Dermal exposure

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the decanting** was 93 mg per 3 kg of decanted product, when considering 1 to 4 decanting times per day and 52.3 mg per 3 kg of decanted product when considering more than 4 decanting times per day.
Since for the control of mice, the quantity of decanted product is 6.3 kg, 93 mg of product was considered. In contrast, for the control of rats, the quantity of decanted product is 12.6 kg corresponding to more than 4 decanting times, leading therefore to consider 52.3 mg of product on fingers/hands.

The following parameters were taken into account:

- Active substance in product: 0.005 %,
- Quantity of decanted product: 12.6 kg for rat (200 g of grains per bait boxes; 63 loading of bait boxes[13]) and 6.3 kg for mouse (100 g of grains per bait boxes; 63 loading of bait boxes),
- Frequency: one manipulation per day,
- Dermal absorption: 1.7 %,
- Body weight: 60 kg.

The quantities of 200 g for the control of rats and 100 g for the control of mice correspond to the validated efficient doses.

Therefore, the systemic dose of chlorophacinone on fingers/hands during decanting is

- For the control of rats: 3.1×10^{-6} mg/kg bw/day,
- For the control of mice: 2.8×10^{-6} mg/kg bw/day.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04mg for the assessment of more than 4 manipulations per day (the agreed number is 63 manipulations in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 63 manipulations per day, the systemic dose of chlorophacinone on fingers/hands during loading is 1.82×10^{-6} mg/kg bw/day for the control of rats and mice because the amount of disposed bait is not taken into account during loading.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 16 cleanings per day, the systemic dose of chlorophacinone on fingers/hands during loading is 8.6×10^{-7} mg/kg bw/day for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

In conclusion, the total systemic dermal exposure is set at 5.8×10^{-6} mg/kg bw/day and 5.5×10^{-6} mg/kg bw/day without PPE for the control of rats and mice, respectively.

Total exposure

[13] HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMII2010

The total systemic exposure resulting from inhalation and dermal contacts with the product is $8.3x10^{-6}$ mg a.s/kg bw/day and $6.9x10^{-6}$ mg a.s/kg bw/day without gloves for the control of rats and mice, respectively.

The estimations above are representative for exposure to CAID GRAIN'TECH in bulk but they represent a very worst case when the product is supplied and applied in sachets. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation. Therefore, only exposure during cleaning can be considered: $8.6x10^{-6}$ mg a.s/kg bw/day without gloves for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

In Annex 6 "Safety for professional operators", results of the exposure calculations for the active substance for the professional user are laid out.

Intended use (MG/PT)	**Exposure scenario**	**PPE**	**Inhalational uptake (mg a.s./kg bw/d)**	**Dermal uptake (mg a.s./kg bw/d)**
PT 14 CAID GRAIN' TECH Grain bait containing 0.005% w/w of chlorophacinone For control of rats in and around buildings, in open areas and in waste sites Supplied in loose	*CEFIC study and HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011*	No	$2.5x10^{-6}$	$5.8x10^{-6}$
PT 14 CAID GRAIN' TECH Grain bait containing 0.005% w/w of chlorophacinone For control of rats in and around buildings, in open areas and in waste sites Supplied in sachets	*CEFIC study and HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011*	No	Not applicable	$8.6x10^{-6}$
PT 14 CAID GRAIN' TECH Grain bait containing 0.005% w/w of chlorophacinone For control of mice in and	*CEFIC study and HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011*	No	$1.5x10^{-6}$	$5.5x10^{-6}$

around buildings, in open areas and in waste sites Supplied in loose				
PT 14 CAID GRAIN' TECH Grain bait containing 0.005% w/w of chlorophacinone For control of mice in and around buildings, in open areas and in waste sites Supplied in sachets	*CEFIC study and HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011*	No	Not applicable	$8.6x10^{-6}$

2.7.3.1.2 Exposure of non-professional users

CAID GRAIN'TECH is used for the control of rats and mice in and around buildings.

Since CAID GRAIN'TECH is also supplied in bulk for non-professional users, but, it can be assumed that there is no decanting phase and no inhalation exposure is expected. Therefore, only dermal exposure during loading and cleaning can be considered for product supplied loose.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04 mg for the assessment of more than 4 manipulations per day and 3.57 mg for the assessment of up to 4 manipulations per day (the agreed number is 5 manipulations in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). As a worst-case, considering 5 manipulations per day, the amount of product of 3.57 mg is used and therefore, the systemic dose of chlorophacinone on fingers/hands during loading is $3.03x10^{-7}$ mg/kg bw/day for the control of rats and mice because the amount of disposed bait is not taken into account during loading.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 5 cleanings in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 5 cleanings per day, the systemic dose of chlorophacinone on fingers/hands during loading is $3.2x10^{-7}$ mg/kg bw/day for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

In conclusion, the total systemic dermal exposure is set at $6.24x10^{-7}$ mg/kg bw/day for the control of both rats and mice.

The estimations above are representative for exposure to CAID GRAIN'TECH without sachet but they represent a very worst case when the product is supplied and applied in sachets. In this case, it

can be assumed that there is no exposure during loading in bait points as the sachet prevents dermal contacts. Therefore, only exposure during cleaning can be considered: $3.2x10^{-7}$ mg a.s/kg bw/day without gloves for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

Intended use (MG/PT)	**Exposure scenario**	**PPE**	**Inhalational uptake (mg a.s./kg bw/d)**	**Dermal uptake (mg a.s./kg bw/d)**
PT 14 CAID GRAIN' TECH Grain bait containing 0.005% w/w of chlorophacinone For control of rats in and around buildings Supplied in loose	*CEFIC study and HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011*	No	Negligible	$6.24x10^{-7}$
PT 14 CAID GRAIN' TECH Grain bait containing 0.005% w/w of chlorophacinone For control of rats in and around buildings Supplied in sachets	*CEFIC study and HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011*	No	Not applicable	$3.2x10^{-7}$
PT 14 CAID GRAIN' TECH Grain bait containing 0.005% w/w of chlorophacinone For control of mice in and around buildings Supplied in loose	*CEFIC study and HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011*	No	Negligible	$6.24x10^{-7}$
PT 14CAID GRAIN' TECH Grain bait containing 0.005% w/w of chlorophacinone For control of mice in and around buildings Supplied in sachets	*CEFIC study and HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011*	No	Not applicable	$3.2x10^{-7}$

In Annex 7 "Safety for non-professional operators and the general public", the results of the exposure calculations for the active substance for the non-professional user and the general public are laid out.

2.7.3.2 Indirect exposure as a result of use of the active substance in biocidal product

Secondary exposure of users and non users could result in the handling of dead rodents. However, this scenario is excluded due to unrealistic assumptions (very low amount of chlorophacinone is expected on the fur because CAID GRAIN'TECH is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for chlorophacinone).
Besides, exposure of non users can occur during ingestion of poison baits. For the scenario "*oral exposure by ingesting bait*", a reverse scenario was calculated. Based on the acute AEL of $3.3x10^{-5}$ mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 100 % (as stated in the Assessment report of chlorophacinone), ingestion of more than 6.6 mg of product per day by an infant is needed to exceed the AEL.

2.7.3.3 Exposure to residues in food

The intended use descriptions of the chlorophacinone-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff. No further data are required concerning the residue behaviour.

2.7.3.4 Combined exposure

Not relevant.

2.7.4 Risk assessment for human health

The estimated exposures for the professional and non professionnal users are compared to the systemic AEL of chlorophacinone set in the Assessment report ($3.3x10^{-5}$ mg/kg bw/day for short-term and $1.7x10^{-5}$ mg/kg bw/day for long-term exposures).

2.7.4.1 Risk for Professional Users

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable when CAID GRAIN'TECH is supplied in loose, even if gloves are not worn (%AEL at 48.8 % and 40.8 % for the control of rats and mice, respectively). Gloves are anyway recommended to help prevent rodent-borne disease.

For CAID GRAIN'TECH supplied and applied in sachet, the risk resulting from the intended use is acceptable, without gloves. Gloves are anyway recommended to help prevent rodent-borne disease. Moreover, the mention "do not open the sachet" has to be added in the label of the product.

Table 2.7.4-1.1: Summary of risk characterisation for professionals for the control of rats

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Bulk formulation (exposure during decanting, loading and cleaning phases)				
Professional	$1.7x10^{-5}$	$8.3x10^{-6}$	48.8	Acceptable

(without gloves)				
Sachet formulation (exposure during cleaning phase)				
Professionnal (without gloves)	$1.7x10^{-5}$	$8.6x10^{-7}$	5.05	Acceptable

Table 2.7.4-1.2: Summary of risk characterisation for professionals for the control of mice

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Bulk formulation (exposure during decanting, loading and cleaning phases)				
Professional (without gloves)	$1.7x10^{-5}$	$6.9x10^{-6}$	40.8	Acceptable
Sachet formulation (exposure during cleaning phase)				
Professionnal (without gloves)	$1.7x10^{-5}$	$8.6x10^{-7}$	5.05	Acceptable

No unacceptable risk was observed for professionals for the control of rats and mice whatever the type of formulation considered (in bulk or in sachet).

2.7.4.2 Risk for non-professional users and the general public

Based on the risk assessment of the active substance, the risk for non professional users resulting from the intended use is acceptable when CAID GRAIN'TECH is supplied in loose, even if gloves are not worn (%AEL at 3.67 % for the control of both rats and mice).

For CAID GRAIN'TECH supplied and applied in sachet, the risk resulting from the intended use is acceptable, without gloves. However, the mention "do not open the sachet" has to be added in the label of the product.

Table 2.7.4-2.: Summary of risk characterisation for non professionals for the control of rats and mice

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Bulk formulation (exposure during decanting, loading and cleaning phases)				
Non Professional (without gloves)	$1.7x10^{-5}$	$6.2x10^{-7}$	3.67	Acceptable
Sachet formulation (exposure during cleaning phase)				
Non Professional (without gloves)	$1.7x10^{-5}$	$3.2x10^{-7}$	1.88	Acceptable

No unacceptable risk was observed for non professionals for the control of rats and mice whatever the type of formulation considered (in bulk or in sachet).

Overall assessment of the risk for the use of the active substance in biocidal product

No unacceptable risk was observed from the intended uses (professional and non professional) whatever the type of formulation considered (in bulk or in sachet) for the treatment of rats and mice. Gloves are anyway recommended to help prevent rodent-borne disease.

2.7.4.3 Indirect exposure as a result of use **of the active substance in biocidal product**

Based on a reverse scenario, more than 6.6 mg of product per day should be ingested by an infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if CAID GRAIN'TECH contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children. Product label ("do not open the sachet") and good practice advise users to prevent access to bait by children

2.7.4.4 Risk for consumers via residues

Considering the intended uses no dietary risk assessment is necessary.

Conclusion of risks characterisation of the product for consumer

The intended use descriptions of the chlorphacinone-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff.

Risk mitigation measures linked to risk assessment for consumer
Do not dispose baits on surfaces in contact with food, feed or drinks and beverages.

2.7.5 Risk for combined exposure

Not relevant.

Conclusion of the risk assessment for human health

No unacceptable risk was observed from the intended uses (professional and non professional) whatever the type of formulation considered (in bulk or in sachet) for the treatment of rats and mice. Gloves are anyway recommended to help prevent rodent-borne disease.

Based on a reverse scenario, more than 6.6 mg of product per day should be ingested by an infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if CAID GRAIN'TECH contains a bittering agent which reduces the likelihood of ingestion, the baits should be placed in areas which do not allow access to children and in secured bait boxes. Product label ("do not open the sachet") and good practice advise users to prevent access to bait by children and infants.

Risk mitigation measures linked to risk assessment for human health

For professional users

- Gloves have to be worn to help prevention against rodent-borne disease
- Bait stations must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Do not open the sachet
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.

- Tamper-resistant bait stations should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Other covered or not covered bait points could be used. These stations must be placed only in areas not accessible to the general public and non-target animals.
- Collect uneaten bait, debris dragged away from the box or bait station and dead rodents, during and after treatment.
- Remove all bait stations (boxes or other bait stations) after the end of treatment.

For non professional users

- Do not open the sachet
- Use only in tamper-resistant bait stations. Tamper-resistant bait stations should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Bait stations must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Collect uneaten bait, debris dragged away from the box or bait station and dead rodents, during and after treatment.
- Remove all bait boxes after the end of treatment

2.8 Risk assessment for the environment

2.8.1 Fate and distribution in the environment of the active substance

The summary of information about the active substance chlorophacinone is carried out with the data from the CAR of chlorophacinone owned by Liphatech S.A.S.

2.8.1.1 Degradation

2.8.1.1.1 Biotic degradation

According to the OECD tests 301F (manometric respirometry test), chlorophacinone is not readily or inherently biodegradable.

In the aquatic compartment, chlorophacinone is assumed to be not biodegradable under environmentally relevant conditions or expected to be biodegradable during sewage treatment processes. So the risk assessment in aquatic compartment is based on the assumption that chlorophacinone is not biodegradable and a half-life is over 365 days.

In the soil compartment, according to the test of US EPA Pesticide Assessment Guidelines, Subdivision N, Paragraph 162-1, chlorophacinone is degraded steadily with an estimated DT_{50} value of 128 days at 12°C (European mean temperature) extrapolated from the DT_{50} value of 47.3 days at 25°C. Degradation of chlorophacinone did not lead to the formation of any significant metabolites (i.e. > 10% AR). Several minor metabolites were observed.

2.8.1.1.2 Abiotic degradation

2.8.1.1.2.1 Hydrolysis in function of pH

According to the test OECD 111 (/EPA OPPTS 835.2100), chlorophacinone is considered stable to hydrolysis with a $DT_{50\ hydrolysis}$ value > 1 year at environmentally relevant temperatures for all pH. Hydrolytic degradation is not expected to be a significant process in the environment.

2.8.1.1.2.2 Photolysis in water

The active substance undergoes rapid photolysis in water. Chlorophacinone is photolysed with a mean DT_{50} value of 0.62 days under artificial sunlight that corresponds to DT50 = 2.2 days under natural summer sunlight (at latitude 50°N) in buffe r solution (pH~7) and to DT50 = 1.3 days under natural summer sunlight (at latitude50°N) in pond w ater (pH~8.4 post sterilisation).
Photolysis of chlorophacinone led to the formation of carbon dioxide and significant levels (i.e. > 10%) of one unidentified degradation products M1, declining thereafter to < 10% AR at 13 days. Since photolysis is a process which occurs mainly in the superficial layer of the water body this metabolite is not be further considered. Photolysis only happens between 10% and 50% (worst case) of the water body, the upper layer. Nevertheless, we considered that the identification of this metabolite should be investigated.

2.8.1.1.2.3 Photodegradation in air

Photodegradation characteristics of the active substance have been calculated using QSAR estimation performed with the Atmospheric Oxidation Program v1.90 (AOPWIN) using the Atkins method. The half-life estimated in air is 14.3 hours. Chlorophacinone does not have any olefinic or acetylenic bonds and therefore it is unlikely that there is a significant photochemical oxidative degradation of chlorophacinone in air via the ozone.
The vapour pressure of chlorophacinone as determined by OECD guideline no. 104 is 4.76×10^{-4} Pa (22.8°C) and Henry's law constant is 0.013725 $Pa.m^3.mol^{-1}$ (based on a water solubility of 13.0 mg/l). Therefore chlorophacinone is not expected to volatilise to air in significant quantities. In conclusion, significant amounts of chlorophacinone are not likely to volatilise or persist in air.

2.8.1.1.2.4 Photodegradation in soil

Chlorophacinone quickly photo-degraded on a soil surface when exposed to an artificial light source, with an equivalent DT_{50} value of 11.1 days (12°C). Degradation of chloroph acinone resulted in the formation of a major metabolite o-phthalic acid (37.1% AR), carbon dioxide (potentially 50% AR) and three minor degradation products (< 10% AR).

2.8.1.2 Distribution

Chlorophacinone adsorbs strongly to soil. The experimentally determined Koc values are from **15,600 to 136,000 mL/g**. On the basis of this study chlorophacinone is indicated as 'non mobile' according to the SSLRC classification index.
It is stated in the CAR of the active substance that there is a discrepancy between the experimentally derived Koc its estimation based on the $K_{ow.}$ Chlorophacinone has a log P_{ow} = 2.42 (pH~7 at 23ºC)**.** The log n-octanol-water partition coefficient (log K_{ow}) is a measure of the hydrophobicity of a chemical. As such, log K_{ow} is a key parameter in the assessment of environmental fate. Estimations of the K_{oc} based on the K_{ow} applying (Q)SAR for soil and sediment would be several orders of magnitude lower than the experimental value retrieved in the adsorption/desorption screening test. The drastic difference reflects that other processes are involved apart from lipophilicity. As a conclusion, adsorption to soil does not depend only on the organic carbon content.

2.8.1.3 Accumulation

The aquatic BCF has been estimated with calculation method because the fish bioconcentration test was not available. The measured value of log Kow value (2.42) allows to calculate an estimated BCF for fish :

BCF_{fish} = 22.75 L/kg

(according to Equation 74, TGD).

The calculations show that chlorophacinone has a relatively low potential to bioaccumulate in aquatic and terrestrial organisms.

2.8.2 Effects on environmental organisms for active substance

2.8.2.1 Aquatic compartment (including water, sediment and STP)

2.8.2.1.1 Aquatic organisms

Chlorophacinone is toxic to very toxic to aquatic organisms. Algae are the less sensitive of the three trophic levels (E_bC_{50} =1.7 and E_bC_{50} = 2.2 mg a.s/L, OECD 201). Chlorophacinone is equally toxic to fish (LC_{50}= 0.45 and 0.71 mg a.s/L, OECD 203) and invertebrates (EC_{50}= 0.64 mg a.s/L, OECD 202).

Table 2.8.2.1.1: Toxicity to freshwater aquatic organisms

Guideline / Test method	Species	Endpoint	Results (mg a.s/l)
OECD 203 / flow through system	*O. mykiss* fish	96 hour LC_{50}	0.45*
OECD 202 / flow through system	*D. magna* aquatic invertebrate	48 hour EC_{50}	0.64*
OECD 201 / static system	*D. subcapitatus* algae	72 hour E_bC_{50}	1.7**

* Measured concentrations

** Calculated from the area under the growth curve

Justification of $PNEC_{water}$:

The $PNEC_{water}$ is derived from the lowest available LC_{50} value = 0.45 mg/L (fish) divided by an assessment factor of 1000 as prescribed in TGD. Therefore,

PNECwater = 4.5×10^{-4} mg a.s./L.

2.8.2.1.2 Sediment dwelling organisms

No ecotoxicological data for sediment-dwelling organisms are available, therefore the equilibrium method is proposed as a sreening approach in order to identify a potential risk to sediment organisms. Nevertheless, as indicated in the adsorption/desorption section, there is a discrepancy between the experimentally derived Koc and its estimation based on the K_{ow}. As no measured data are available for PECsediment or for calculation of a PNECsediment, the CAR of chlorophacinone

recommand a qualitative risk assessment assuming that the sediment compartment is covered by the aquatic compartment.

Justification of $PNEC_{sediment}$:
No PNECsediment could be extrapolated for Chlorophacinone.

2.8.2.1.3 STP micro-organisms

Chlorophacinone did not cause any effects on the activated sludge respiration inhibition up to the nominal concentration of 1000 mg/L (OECD 209). The EC_{15} (3 h) of chlorophacinone was determined at 775 mg a.s/l (measured concentration) in a static test with activated sludge. It has to be taken into account that this value is far above the water solubility limit which is 334 mg a.s./L. Therefore, the water solubility limit has been used in the CAR of chlorophacinone for the $PNEC_{microorganisms}$ derivation instead of the nominal concentration.

Justification of $PNEC_{micororganisms}$:
The $PNEC_{micro\text{-}organisms}$ is derived from the water solubility of chlorophacinone divided by an assessment factor of 10. Therefore,
PNECmicroorganims = 34.4 mg/L.

2.8.2.2 Terrestrial compartment

Chlorophacinone caused no toxic effects on earthworms up to the nominal concentration of 1000 mg/kg dry weight soil (OECD 207). The 14-day LC50 of chlorophacinone was greater than 1000 mg/kg dry soil the highest concentration applied, that corresponds to a normalized value of 300 mg/kg wet soil to represent a standard soil with an average organic matter content of 3.4%.

Table 2.8.2.2.: Toxicity to soil organisms

Guideline / Test method	Species	Endpoint / Type of test	Exposure design	duration	Results (mg a.s/kg dwt soil) NOEC	LC_{50}	Reference
OECD 207	*Eisenia foetida*	LC_{50}	soil exposure	14 days	309	> 1,000 >340 (standardised)	CAR a.s. Doc. III-A 7.5.1.2-01

Justification of $PNEC_{soil}$:
The $PNEC_{soil}$ is derived from the experimental data. An assessment factor of 1000 was applied to the LC_{50} > 300 mg/kg wet soil issued from an earthworms study to derive the $PNEC_{soil}$.
$PNEC_{soil}$ = 0.30 mg/kg wet weight
In the CAR of chlorophacinone, it is considered not appropriate to calculate the $PNEC_{soil}$ using the equilibrium partitioning method due to the uncertainty associated to the discrepancies between the measured K_{oc} and its estimation based on the K_{ow}.

2.8.2.3 Non compartment specific effects relevant to the food chain

As already stated in the previous section, chlorophacinone has a relatively low potential to bioaccumulate in aquatic and terrestrial organisms.

The exposure of chlorophacinone directly to non-target birds and mammals (primary poisoning) and indirectly via target rodent carcasses (secondary poisoning) is considered a critical aspect of the risk assessment.

Table 2.8.2.3.: Toxicity to birds and mammals (key studies)

Guideline / Test method	Species	Endpoint / Type of test / Duration	Results NOEC/NO(A)EL	LD/C_{50}	Reference
SETAC (1995)	Bobwhite quail (*Colinus virginianus*)	LD_{50}/ acute oral	NOEC < 100 mg a.s/kg bw	LD_{50} = 257 mg a.s/kg bw	CAR a.s. Doc. A-III 7.5.3.1.1-02
OECD 205*	Bobwhite quail (*Colinus virginianus*)	LC_{50}/ short-term dietary/ 5 days	NOEC = 10 mg a.s/kg food	LC_{50} = 95 mg a.s/kg food Eqivalent to 17.3 mg a.s·kg bw^{-1}·d^{-1}	CAR a.s. Doc. III-A 7.5.3.1.2-01
	Beagle dog	Acute oral toxicity	-	LD_{50} « 2 mg a.s/kg bw	CAR a.s. Doc. III-A 6.1.1-02
	*Rattus norvegicus**	Subchronic oral toxicity 11 to 16 weeks	NO(A)EL=0.005 mg a.s/kg bw LO(A)EL=0.010 mg a.s/kg bw	-	CAR a.s.Doc.III-A 6.4.1-01

2.8.2.3.1 Primary poisoning

Acute/short-term qualitative assessment

A qualitative assessment agreed upon in the TM has included as a first step in assessing the acute risk.

The relevancy of the acute risks has come out with the incidents occurred last February 2007 in Spain due to the direct application by farmers of a formulation based on chlorophacinone registered as a pesticide product in Spain. These incidents confirm the need of an acute risk assessment for chlorophacinone. The evaluation of a short-term (single intake, acute exposure) risk is considered a key element due to its high acute toxicity. Therefore, a proposal for a short-term risk assessment in addition to the long-term risk assessment has been included developed by the RMS in the CAR of chlorophacinone.

Regarding the qualitative assessment only a description of the toxicity of the substance compared to the possible single uptake is presented instead of carrying out a quantitative risk assessment. It is stressed in the CAR that this qualitative assessment is a simple comparison of the acute exposure situation with single dose LD_{50} values. The qualitative risk assessment is not intended to be used for risk characterisation; no $PNEC_{oral}$ shall be derived and hence no PEC/PNEC ratio can be established. This comparison only give a first indication of the acute toxicity of the substance. This qualitative assessment is not intended to be used for the risk characterisation of primary and secondary poisoning of rodenticides and shall not be used for a comparative assessment.

For mammals the acute toxicity to **dog LD50 << 2 mg a.s. /kg bw** is used in the qualitative assessment for comparisons with estimated daily uptakes of chlorophacinone (ETE, mg a.s. /kg bw).

For birds the acute toxicity to Bobwhite quail *C. virginiatus* **LD50= 257 mg a.s. /kg bw** is used in the qualitative assessment for comparisons with estimated daily uptakes of chlorophacinone (ETE, mg a.s. /kg bw).

Long-term assessment

Concerning birds, the 5-days LC_{50} of chlorophacinone is 95 mg a.s/kg food based on the 5-days short-term dietary LC_{50} study in Bobwhite quail (*Colinus virginianus*).
The $PNEC_{oral}$ is derived using using the result of this study divided with the assessment factor 3000 which results in a
$PNEC_{oral}$ for birds = 0.03 mg/kg food equivalent to
$PNEC_{oral}$ for birds = 0.006 mg/kg bw/day.

Concerning mammals, the most sensitive organism is the rat in the subchronic oral test (11 to 16 weeks) with a NO(A)EL of 0.005 mg a.s/kg bw.
According to the decision taken at TM, the NOAEL is transformed into a NOEC using a TGD factor of 20, and the AF_{oral} of 90 is applied to this NOEC, which results in a

$PNEC_{oral}$ for mammals = (0.005 x 20)/90 = **0.0011 mg/kg food equivalent to**
$PNEC_{oral}$ for mammals = 0.00005 mg/kg bw/day.

In addition, Estimated No Effect Level ENEL ranging from 0.00006 to 0.00017 mg as/kg predator bw
have been estimated.

2.8.2.3.2 Secondary poisoning

Acute/short-term qualitative assessment

For mammals the acute toxicity to **dog LD50 << 2 mg a.s. /kg bw** is used in the qualitative acute assessment for comparisons with estimated daily uptakes of chlorophacinone (ETE, mg a.s. /kg bw).

For birds the acute toxicity to Bobwhite quail *C. virginiatus* **LD50= 257 mg a.s. /kg bw** is used in the qualitative acute assessment for comparisons with estimated daily uptakes of chlorophacinone (ETE, mg a.s. /kg bw).

Long-term assessment

Concerning birds, no reliable long-term toxicity studies on birds were submitted in the CAR, and therefore it is stated that the only possible comparisons are with the PNEC estimated from short-term studies which is supported in the CAR by additional information. The 5-days LC_{50} of chlorophacinone is 95 mg a.s/kg food based on the 5-days short-term dietary LC_{50} study in Bobwhite quail (*Colinus virginianus*).
Therefore, the $PNEC_{oral}$ is derived using the result of this study divided with the assessment factor 3000 which results in a
$PNEC_{oral}$ for birds = 0.03 mg/kg food equivalent to
$PNEC_{oral}$ for birds = 0.006 mg/kg bw/day

For mammals, the most sensitive organism is the rat in the subchronic oral test (11 to 16 weeks) with a NO(A)EL of 0.005 mg/kg bw. According to the decision taken at TM, the NOAEL is transformed into a NOEC using a TGD factor of 20, and the AF_{oral} of 90 is applied to this NOEC, which results in a

$PNEC_{oral}$ for mammals = (0.005 x 20)/90 = **0.0011 mg/kg food equivalent to**
$PNEC_{oral}$ for mammals = 0.00005 mg/kg bw/day.

In addition, Estimated No Effect Level ENEL ranging from 0.00006 to 0.00017 mg as/kg predator bw have been estimated.

2.8.2.4 Summary of PNECs of the active substance chlorophacinone

Table 2.8.2.4.: Summary of the chlorophacinone (a.s.) PNECs

Compartment		Test Value	AF	PNEC
Aquatic	PNECwater	LC_{50} =0.45 mg a.s. /L	1000	4.5×10^{-4} mg a.s. /L
	$PNEC_{sediment}$	Not available		Not available
	$PNEC_{STP}$	water solubility limit = 344 mg a.s. /L	10	34.4 mg a.s. /L
Terrestrial	$PNEC_{soil}$	LC_{50} >300 mg a.s. /kg ww soil	1000	0.30 mg a.s. /kg ww soil
Primary and secondary poisoning	$PNEC_{oral\ for\ birds}$	LC_{50} = 95 mg a.s. /kg bw/d bobwhite quail dietary 30 days	3000	0.03 mg a.s. /kg food
	$PNEC_{oral\ for\ mammals}$	NOAEL =0.005 mg a.s. bw/day Rat/ subchronic 90 days NOEC = 0.005*20= mg 0.1 a.s. bw/day	90	0.0011 mg a.s. /kg food
	$ENEL_{mammals}$			0.00017-0.00006 mg a.s. /kg bw

2.8.2.5 Atmosphere

No data are available on the biotic effects in the atmosphere. Chlorophacinone is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical or chemical properties.

2.8.2.6 PBT and ED assessment

As stated in the previous section, chlorophacinone is classified as not readily biodegradable, and it is considered stable to hydrolysis at environmentally relevant temperatures. Hence, the screening criteria for persistence is met.

Rapid photolysis in water and soil are reported with DT_{50} value of 2.2 days at 25ºC and pH~7 and , a DT_{50} of 11.1 days at 12ºC respectively. Degradation studies are reported for soil $DT_{50\ lab\ soil}$ (25ºC) = 47.3 days (corresponding to 128 days at 12℃) , b ut not for water-sediment or freshwater, thus a definitive assessment of the P criteria cannot be established.

The log K_{ow} = 2.42 at pH~7 and 23ºC indicating no potential for bioaccumulation. The substance does not fulfil the B criterion. This conclusion is confirmed by the information from the toxicokinetic studies on mammals.

In conclusion, since chlorophacinone does not meet criteria B, it is not considered a PBT candidate.

According to the CAR, the active substance chlorophacinone is not an endocrine disruptor.

2.8.3 Effects on environmental organisms for biocidal product

It is important to notice that the applicant did not provide ecotoxicological data about the biocidal product CAID GRAIN' TECH. So all the risk assessment is based on the data obtained from the active substance chlorophacinone.

Denatonium benzoate is used in the biocidal product as bittering agent. This substance is classified as "Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment" in the frame of the Directive 91/414/EEC. Nevertheless in the concentration used in CAID GRAIN' TECH, the substance does not contribute to the classification of the biocidal product.

No other substance used in the biocidal product is classified for the environment.

Therefore, FR CA considered that the effects of chlorophacinone outweigh those of the non-active components of the product and that the effects assessment for the product CAID GRAIN' TECH can be extrapolated from the effects assessment of the active substance chlorophacinone.

2.8.4 Environmental exposure assessment

In accordance with EUBEES ESD for PT14 (2003) and TGD for Risk Assessment (2003), a quantitative approach is used in the risk assessment for CAID GRAIN' TECH biocidal product. Quantitative PEC estimations are performed for the relevant environmental compartments for chlorophacinone. The different PEC values are derived from model calculations, but available measured data (e.g. residues of chlorophacinone in rat) are also taken into consideration.

The environmental exposure assessment has been conducted based on the fate and distribution properties of the active substance, chlorophacinone, as determined from laboratory studies. The predicted environmental concentration (PEC) of chlorophacinone has been estimated, where appropriate, in various environmental compartments (surface water, groundwater, sediment, air and soil) following realistic worst case and, where appropriate, normal case usage scenarios.

CAID GRAIN' TECH as red grain bait LR0191 contains 50 mg/kg chlorophacinone as the active substance. Chlorophacinone grain bait formulations are composed of heterogeneous solid cereal grains which are dyed red. The grain bait formulations are available ready to use either as loose grains or in sachets (see application form for further details on packaging).

The product is intended to be used to control:

- *Rattus norvegicus* (Norway rat, Brown rat);
- *Rattus rattus* (Black rat);
- *Mus musculus* (House mouse).

CAID GRAIN' TECH is used in the following areas:

- In and around buildings (professional and non-professional use).
- Waste dump (landfill) perimeters (professional use only)
- Open areas (professional use only)

According to the product instructions, CAID GRAIN' TECH can be supplied with sachets for professional and amateur and without sachet for professional users only.

From the intented uses, the terrestrial compartment is the relevant compartment of release. The risks are also calculated for primary and secondary poisoning.

2.8.4.1 PEC in surface water, sediment, STP for uses in and around building, open area and waste dumps

Contamination of surface water or sediment with chlorophacinone from the placing of CAID GRAIN' TECH in and around buildings, in open areas and in waste dumps is not expected to occur. Negligible exposure of surface water is stated in the EUBEES 2 emission scenario document and consequently estimates of chlorophacinone concentrations in surface water or sediment have not been calculated for these scenarios.

2.8.4.2 PEC in air

For chlorophacinone, the estimated half-life for the hydroxyl reaction in air is 14.3 hours, the vapour pressure as determined by OECD 104 is $4.76 \cdot 10^{-4}$ Pa (22.8℃) and the Henry's law constant is 0.013725 $Pa.m^3.mol^{-1}$ (based on a water solubility of 13.0 mg a.s/L). Therefore chlorophacinone is not expected to volatilise to air in significant quantities following use in any of the usage scenarios (i.e. in and around buildings, open areas and waste dumps) and the potential concentration of chlorophacinone in air is considered to be negligible.

2.8.4.3 PEC in the terrestrial compartment (soil and groundwater)

The PEC values for chlorophacinone in soil arising from the various usage scenarios (in and around buildings, open areas and waste dumps) are considered, as follows:

2.8.4.3.1 In and around buildings

Exposure of the terrestrial compartment (soil) will occur when CAID GRAIN' TECH is deployed outdoors. EUBEES 2 considers a scenario that entails outdoor baiting with grain bait around a farm building. In this situation, exposure is assumed to arise through a combination of transfer (direct release) and deposition *via* urine and faeces (disperse release) onto soil. Direct release is estimated to amount to 1.0% of the total bait deployment during the entire campaign, concentrated within 10 cm of the individual secured bait points. Similarly, EUBEES 2 considers that 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil *via* urine and faeces.

The maximum application rate for CAID GRAIN' TECH containing 50 mg chlorophacinone/kg entails the deployment of 200 g bait in each of ten secured bait points spaced 4 m apart for rats and 100 g in each secured bait points spaced 1 m for mice. EUBEES 2 assumes that direct release is concentrated in a 10 cm strip in front of and to both sides of each bait point (0.09 m^2).

To estimate the concentration of chlorophacinone in soil arising from disperse release, it is assumed that most of the activity of the target rodents is confined to a strip of ground running along the length of the baited wall and extending to 10 m in front of it (presenting an area of 440 m^2 for rats and 110 m^2 for mice).

EUBEES 2 considers two levels of baiting. In the first, described as the "realistic worst-case", the campaign lasts 21 days and secured bait points (initially filled on day 1 and repeatedly and completely emptied by the target rodents) are refilled on days 3, 7, 14 and 21. In the other, "typical" scenario, bait consumption progressively declines as the campaign proceeds, such that the replenishments made on days 3, 7, 14 and 21 represent 100%, 25-50%, 10% and 0%, respectively, of the quantity initially deployed on day 1. It should be noted that the "typical" scenario is more representative of the consumption pattern for a potent anticoagulant rodenticide such as chlorophacinone, as demonstrated by the field studies.

In both scenarios, the direct and disperse chlorophacinone releases ($Elocal_{soil}$, mg) to the relevant soil surfaces may be calculated according to:

$$Elocal_{soil} = Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refill} \times F_{release,\ soil},$$

where:

Q_{prod} = weight of CAID GRAIN' TECH (200 g or 100 g) per secured bait point;
Fc_{prod} = concentration of chlorophacinone in the grain bait (0.050 mg/g);
N_{sites} = number of secured bait points (10);
N_{refill} = number of refills during the campaign (5 in "realistic worst-case" and 1.5 in "typical" scenario)
$F_{release,\ soil}$ = fraction released to soil (0.01 for direct release and 0.9 for disperse release).

Local concentration in soil due to direct release after a campaign:

$$Clocal_{soil\text{-}D} = \frac{Elocal_{soil\text{-}D\text{-}campaign} \times 10^3}{AREA_{exposed\text{-}D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites}}$$

where:

$AREA_{exposed\text{-}D}$ = area directly exposed to rodenticide (0.09 m^2);
$DEPTH_{soil}$ = depth of soil (0.1 m)
N_{sites} = number of sites (10);
RHO_{soil} = density of exposed soil (1700 kg/m^3)

Concentration in soil due to indirect (disperse) release after a campaign:

$$Clocal_{soil\text{-}ID} = \frac{Q_{prod} \cdot Fc_{prod} \cdot N_{sites} \cdot N_{refil} \cdot F_{release\text{-}ID,soil} \cdot (1 - F_{release\text{-}D,soil})}{AREA_{exposed\text{-}ID} \cdot DEPTH_{soil} \cdot RHO_{soil}}$$

where:

Q_{prod} = weight of CAID GRAIN' TECH (200 g or 100 g) per secured bait point;
Fc_{prod} = concentration of chlorophacinone in the grain bait (0.050 mg/g);
$AREA_{exposed\text{-}ID}$ = area directly exposed to rodenticide (440 or 110 m^2);
$DEPTH_{soil}$ = depth of soil (0.1 m)
N_{sites} = number of sites (10)

N_{refil} = number of sites (5)
RHO_{soil} = density of exposed soil (1700 kg/m^3)
$F_{releaseD, soil}$ = fraction released directly to soil (0.01)
$F_{release-ID, soil}$ = fraction released indirectly to soil (0.9)

Considering the adsorption potential of the substance, the lowest Koc value reported (15 600 L/kg) has been used to derive the PEC for groundwater.

Table 2.8.4.3.1: PEC chlorophacinone in soil and porewater for uses in and around buildings

			ESD Default parameters: realistic worst-case		**Refined and specific parameters: typical scenario**		
	Symbol	**Variable/parameters**	**Rat**	**Mouse**	**Rat**	**Mouse**	**Unit**
INPUT	$Q_{prod:}$	Amount of product used in control operation for each bait box	200	100	200	100	[g]
	$Fc_{product}$:	Concentration of active substance in product	0.05	0.05	0.05	0.05	[$g.kg^{-1}$]
	Nsites:	Number of application sites	10	10	10	10	[-]
	N_{refil}:	Number of refilling times	5	5	1.5	1.5	[-]
	$F_{release-D, soil}$:	Fraction of product released directly to soil	0.01	0.01	0.01	0.01	[-]
	$F_{release-ID, soil}$:	Fraction released indirectly to soil	0.9	0.9	0.9	0.9	[-]
	Distance	Distance between 2 bait points	4	1	4	1	[m]
	$AREA_{exposed-D}$:	Area directly exposed to rodenticide originating from one bait box	0.09	0.09	0.09	0.09	[m^2]
	$AREA_{exposed-ID}$:	Area indirectly exposed to rodenticide	440	110	440	110	[m^2]
	$DEPTH_{soil}$:	Depth of exposed soil	0.1	0.1	0.1	0.1	[m]

	RHO_{soil}:	Density of exposed soil	1700	1700	1700	1700	[$kg.m^{-3}$]
OUTPUT	$Elocal_{soil-campaign, direct}$:	Direct emission to soil from a campaign	5.00E-03	2.50E-03	1.50E-03	7.50E-04	[$g.camp^{-1}$]
OUTPUT	$Elocal_{soil-campaign, indirect}$:	Indirect emission to soil from a campaign	4.46E-01	2.23E-01	1.34E-01	6.68E-02	[$g.camp^{-1}$]
OUTPUT	$Elocal_{soil-campaign}$:	Total emission to soil from a campaign	4.51E-01	2.25E-01	1.35E-01	6.76E-02	[$g.camp^{-1}$]
OUTPUT	$Clocal_{soil-D}$	*Local concentration in soil due to direct release after a campaign:*	3.27E-02	1.63E-02	9.80E-03	4.90E-03	[$mg.kg^{-1}_{wwt}$]
OUTPUT	$Clocal_{soil-ID}$	*Concentration in soil due to indirect (disperse) release after a campaign:*	5.96E-03	1.19E-02	1.79E-03	3.57E-03	[$mg.kg^{-1}_{wwt}$]
OUTPUT	$Clocal_{soil}$	*Worst case total concentration in soil*	3.86E-02	2.83E-02	1.16E-02	8.48E-03	[$mg.kg^{-1}_{wwt}$]
OUTPUT	Koc	*Partition coefficient organic carbon-water*	15 600	15 600	15 600	15 600	[$L.kg^{-1}$]
OUTPUT	$Clocal_{soil\ mean\ concentration}$	*Mean concentration in soil*	6.02E-03	1.20E-02	1.81E-03	3.61E-03	[$mg.kg^{-1}_{wwt}$]
OUTPUT	Kp_{soil}	*Partition coefficient solid-water in soil*	3.12E+02	3.12E+02	3.12E+02	3.12E+02	[$L.kg^{-1}$]
OUTPUT	$K_{soil\ water}$	*Soil-water partitioning coefficient*	4.68E+02	4.68E+02	4.68E+02	4.68E+02	[$m^3.m^{-3}$]
OUTPUT	$PEClocal_{soil, porew}$	*Worst case concentration in groundwater (based on the total concentration in soil)*	1.40E-04	1.03E-04	4.21E-05	3.08E-05	[$mg.L^{-1}$]

	PEClocal soil, porew	*Mean concentration in groundwater (based on mean concentration in soil)*	2.19E-05	4.37E-05	6.56E-06	1.31E-05	[mg.L^{-1}]

2.8.4.3.2 Open areas

CAID GRAIN' TECH is applied in open areas by inserting inside the openings of the tunnels of the target rodents. According to the EUBEES 2 scenario, the use near the openings of the tunnels is covered by the assessment of the scenario "in and around buildings" with bait box. Thus this section "Open areas" only assesses the use inside the tunnels during which according to the scenario presented in EUBEES 2, two such treatments would typically be applied in the space of six days. Bait deployment comprises 200 g of grain per application per tunnel entrance for rats and 100 g for mice. Based on a tunnel of 8 cm diameter, worst-case soil exposure is assumed to occur to a depth of 10 cm from the contact half (*i.e*. the burrow floor) of a 30 cm tunnel section in which the bait is placed. This section of tunnel floor is assumed to receive an input corresponding to 5% of the product during application and a further 20% as the bait is consumed.

Local emission of active substance to soil during a campaign:

$$Elocal_{soil\text{-}campaign} = Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times (F_{release,soil,appl} + F_{release,soil,use})$$

Where the fraction of product released to soil during application is 5% and the fraction of product released to soil during use is 20%.
where:

Q_{prod} = weight of CAID GRAIN' TECH (200 g rats or 100 g mice) per secured bait point;
Fc_{prod} = concentration of chlorophacinone in the grain bait (0.050 mg/g);
N_{sites} = number of application sites (1);
N_{refill} = number of refills during the campaign (2)
$F_{release,\ soil,\ appl}$ = fraction released to soil (0.05)
$F_{release,\ soil,\ use}$ = fraction released to soil (0.20)

$Elocal_{soil\text{-}campaign}$ = 200 g product · 0.05 mg a.s./g product · 1 · 2 · (0.05 + 0.20) = 5 mg a.s.

Local concentration in soil after a campaign:

$$Clocal_{soil} = \frac{Elocal_{soil\text{-}campaign}}{Vsoil_{exposed} \cdot RHO_{soil}}$$

Where the default soil volume exposed to rodenticide is 0.0085 m^3 and the density of wet exposed soil 1700 kg·m^{-3}

$$Clocal_{soil} = \frac{5 \text{ mg a.s.}}{0.0085 \text{ m}^3 \text{ soil x } 1{,}700 \text{ kg/m}^3 \text{ soil}} = 0.346 \text{ mg a.s./kg wwt soil}$$

Table 2.8.4.3..2: Concentrations of chlorophacinone in soil following baiting in open areas with grain baits

Baiting scenario (EUBEES 2)	Chlorophacinone applied (mg as)[a]	Total direct deposition (mg as)[b]	PECsoil (mg chlorophacinone /kg wwt soil)[c]
Worst-case - Rats	20.0	5.0	0.346
Worst-case - Mice	10	2.5	0.173

[a] based on 2 x 200 g or 2 x 100 g grains containing 50 mg chlorophacinone/kg;
[b] based on inputs during application and consumption giving a combined deposition of 25%;
[c] based on uniform distribution in a semi-cylinder of soil of 4 cm and 14 cm inner and outer radius, respectively, 30 cm length (volume: 8 500 cm^3) and a wet soil bulk density of 1.7 g/cm^3.

The predicted concentration of 0.346 and 0.173 mg chlorophacinone/kg soil represents the worst-case in the immediate vicinity of each bait application. However, since CAID GRAIN' TECH is specifically formulated to maintain bait integrity in damp environments, the extent of release of chlorophacinone into the floor of the tunnel is likely to be considerably less than the 25% suggested in EUBEES 2. Moreover, as the target rodents will eat and translocate portions of edible baits, and since much of the active substance will subsequently be excreted over a wide area outside the tunnel network, soil concentrations elsewhere will be considerably lower.

As this type of application concerns only a restricted area, groundwater contamination was not deemed relevant for the use in open area.

2.8.4.3.3 Waste Dumps

CAID GRAIN' TECH is deployed in waste-dumps and land-fill sites to control populations of rats. EUBEES 2 suggests a scenario in the event of an infestation outbreak that entails 40 kg of grains protected inside bait boxes distributed over an area of 1 ha, with a total of seven such applications per year. Soil exposure is assumed to arise through a combination of deposition via urine and faeces plus the rodenticide contained in the carcasses of poisoned target rodents. In general, ninety percent of the total amount of rodenticide consumed by the target rodents over the duration of each baiting campaign is assumed to enter soil over the 1 ha surface.

According to the label instructions, the product can be applied at the dose rate of 200 g every 3 meters. Considering these parameters, the maximal quantity of product applied by hectare is 229 kg.

According to the two worst-case scenarios, the total chlorophacinone release ($Elocal_{soil}$, mg) to the soil surface may be calculated according to:

$$Elocal_{soil} = Q_{prod} \times Fc_{prod} \times N_{app} \times F_{release,\ soil},$$

Where:

Q_{prod} = the total weight of grains (40 kg EUBEES 2 ESD or 229 kg label instructions)
Fc_{prod} = the concentration of chlorophacinone in the product (50 mg/kg)
N_{app} = the number of applications (7)
$F_{release,\ soil}$ = the fraction released to soil (0.9).

However, these two worst-case deposition scenarios are unrealistic on two counts. First, it assumes that the 1 ha baited perimeter strip (where the deposition occurs) remains static, whereas in reality it is likely to shift as areas that become filled up with waste are capped with soil. Secondly, it assumes that the rodenticide used in every baiting campaign contains the same active substance and, thirdly, penetration is limited to a depth of 10 cm from the soil surface, despite the fact that the management of waste dump and landfill sites commonly involves the mechanical disturbance and movement of considerable quantities of soil.

Table 2.8.4.3.3.1

: Worst-case concentrations of chlorophacinone in soil following baiting around waste dumps/landfills with grain baits considering the ESD parameter or the label instructions

Baiting scenario	Release to soil (g chlorophacinone / ha) $Elocal_{soil}$	PECsoil (mg chlorophacinone/kg wwt soil)[a]
Default parameters (EUBEES 2)[b]	12.6	0.0074
Label instructions	72.1	0.0424

[a] based on uniform distribution to 10 cm depth and wet soil bulk density of 1.7 g/cm^3;

Concentrations in porewater are calculated for the application in waste dumps considering the PECsoil values and the TGD equations. Considering the adsorption potential of the substance, the lowest Koc value reported (15 600 L/kg) has been used to derive these PEC values.

Table 2.8.4.3.3.2: Worst-case concentrations of chlorophacinone in porewater following baiting in waste dumps/landfills with grainbaits considering the ESD parameter or the label instructions

Baiting scenario	PECsoil (mg chlorophacinone/kg wwt soil)	PECporewater (µg/L)
Default parameters (EUBEES 2)[b]	0.0074	2.69E-02
Label instructions	0.0424	1.54E-01

The exposure assessment has also been done considering the degradation of the substance with time (DT_{50} 128 days) and PEC values were calculated just after the 7th application with a fraction accumulation in the interval between two applications (Facc) of 0.722.

Table 2.8.4.3.3.3: Concentrations of chlorophacinone in porewater considering degaradtion following baiting in waste dumps/landfills with grainbaits considering the ESD parameter or the label instructions

Baiting scenario	PECsoil (mg chlorophacinone/kg wwt soil)	PECporewater (µg/L)
Default parameters (EUBEES 2)[b]	0.0074	1.24E-02
Label instructions	0.0424	7.11E-02

2.8.4.4 Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

The exposure and risk assessment for the primary and secondary poisoning presented below was mainly based the Annex I dossier for the active substance inclusion considering that chlorophacinone concentration (0.005% of chlorophacinone in the product) is identical in the product CAID GRAIN' TECH and in the representative product (P2) presented for the Annex I inclusion.

Non-target vertebrates may be exposed to grain baits containing chlorophacinone either directly by ingestion of exposed grains (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain chlorophacinone residues (secondary poisoning). The use of rodenticides meant for killing selected pest mammals has to be considered a general hazard to non-target mammals and birds as well. This hazard is related to the selectivity of the rodenticide for the target species, which obviously depends on the mode of action. Chlorophacinone is an anticoagulant agent; it uncouples oxidative phosphorylation depressing hepatic synthesis of prothrombin and clotting factors VII, IX and X and, it causes direct damage to capillary permeability. This mode of action is quite general and this family of anticoagulant rodenticides are expected to be toxic for non-target rodents, other mammals and birds. The available data confirm the toxicity of chlorophacinone to non-rodent mammals; while birds seem to be much less sensitive. In addition to susceptibility to or tolerance of the rodenticide among mammalian and avian species; additional differences may be due to the diets, feeding habits, ecological or other factors.

Based on toxicity data chlorophacinone is very toxic for non-target vertebrates and requires an in-depth risk assessment for this group. The following quantification of risk considers situations where non-target vertebrates may gain access to grain baits directly (primary exposure) or to rodents that have consumed grain baits (secondary exposure).

Concerning the primary poisoning, rodenticidal baits consist of cereals, grease or wax; therefore direct exposure is relevant mainly for rodents and seed eating birds. As rodenticides are toxic to non-target species an exposure assessment that is based on exclusive feeding on the bait is expected to come in almost all cases to the conclusion of potential risk. Consideration to the accessibility of baits and attractivity are two obvious refinement steps. In relation to attractivity, rodenticidal baits are designed to be attractive for rodents, so avoidance should not be expected. The notifier states that **"often a bitter agent is added which repeals children and carnivores but is unable to deter non-target rodents and birds**" but no studies have been submitted to support it. Nevertheless, the bait could be unattractive to birds to a certain degree due to colour, consistency and other factors.

In the CAR for active substance it is stated that the applicant has drawn the attention to several published papers in relation to the appeal of the baits to non-target organisms:

Although primarily intended to preserve bait integrity in moist environments, presentation of chlorophacinone in a consolidated matrix of paraffin wax and grain has the added benefit of

reducing the appeal of the bait to non-target organisms that would otherwise readily consume loose chlorophacinone-treated seeds[14].

It has long been known that visual stimuli are important to birds in the selection of novel foods and bait blocks are consequently unlikely to be visually appealing to birds as food based on their shape, texture and colour (WHO, 1995)[15]. According to Harrison *et al*. (1988)[16], wild birds presented with a selection of foods resembling wheat-based rodenticide baits were generally indifferent to whole, non-coloured wax blocks and consumption amounted to less than 5% of the quantity offered. Inclusion of a red colorant in chlorophacinone bait blocks is likely to reduce their appeal as a potential food item still further: several studies have shown that birds prefer, when given a choice, undyed grains and seeds, compared to those artificially coloured. Thus Gemmeke (2000)[17] noted that pigeons, Japanese quails, various crows, jackdaws, magpies and pheasants presented with a choice of natural and dyed seeds of various crop species all preferred the untreated option, and that seeds artificially coloured green, grey, black, pink, blue, violet and brown-violet were either untouched or only eaten in small (*ca*. 10%) amounts.

Similarly, Moran (1999)[18] found that pigeons and partridges preferred undyed grains of their favoured seeds (whole-grain wheat and sorghum, respectively), but that pigeons showed no colour discrimination when only the seeds of a species normally avoided were available. Although species, sex and even individual preferences will modulate the response of birds to colour, there is evidence from the literature that colours in the middle of the visible colour spectrum range are generally better deterrents than other colours. For example, Marsh (1985)[19], (citing Kalmbach (1943)[20], Kalmbach and Welch (1946)[21], Caithness and Williams (1971)[22], Pank, (1976)[23] and Brunner and Coman (1983)[24]) reported that green and yellow were particularly effective colours for discouraging intake of rodenticidal baits and suggested that the deterrent effect of the colorant may in some cases be a visual cue coupled with taste-conditioned aversion. Birds are therefore considered to be at low risk of primary poisoning. Because of the very low likelihood that bait blocks will be ingested by birds, the primary poisoning risks to birds are not quantified.

However it was concluded in the CAR for chlorophacinone that there is not enough evidence for assuming that the characteristics of the baits are enough for avoiding bird exposure. Therefore, it is considered necessary to perform the primary poisoning risk assessment to birds as specific confirmatory data were not provided in the authorisation dossier.

The acute, short-term and long-term risks are assessed for mammals and birds. The long-term risk for birds is based on the application of a large uncertainty factor to a short-term results as no reliable reproduction studies on birds are available. The most important effect of this anticoagulant

[14] Marsh, R.E. (1985). Techniques used in rodent control to safeguard nontarget wildlife. In: Transactions of the Wildlife Society Annual Meeting (W.F. Ladenslayer Jr.: Ed). January 25-26. Monterey, CA., USA.
[15] WHO (1995). Anticoagulant Rodenticides (Environmental Health Criteria 175). International Programme on Chemical Safety. World Health Organisation, Geneva.
[16] Harrison, E.G., Porter, A.J. and Forbes, S. (1988). Development of methods to assess the hazards of a rodenticide to non-target vertebrates. Proceedings of the British Crop Protection Symposium.
[17] Gemmeke, H. (2000). Fraßabschreckende Wirkung von gefärbtem Saatgut auf Vögel. http://www.bba.de/oekoland/oeko3/voegel.htm
[18] Moran, S. (1999). Rejection of dyed field rodent baits by feral pigeons and chukar partridges. *Phytoparasitica* **27** (1): 9-17
[19] Marsh, R.E. (1985) Techniques used in rodent control to safeguard nontarget wildlife.
[20] Kalmbach, E.R. 1943. Birds, rodents and colored lethal baits. Transactions of the North American Wildlife Conference, 8: 408-416.
[21] Kalmbach, E.R. and Welch, J.F. (1946). Colored rodent baits and their value in safeguarding birds. *J. Wildlife Management*, 10: 353-360.
[22] Caithness, T.A. and Williams, G.R. (1971). Protecting birds from poisoned baits. New Zealand Department of Internal Affairs, Wildlife Publication No. 129.
[23] Pank, S. (1976). Effects of seed and background colours on seed acceptance by birds. *J. Wildlife Management*, **40**: 769-774.
[24] Brunner, H. and Coman, B.J. (1983). The ingestion of artificially coloured grain by birds, and its relevance to vertebrate pest control. *Australian Wildlife Research* **10**: 303-310.

rodenticide on birds is lethality, as it has been demonstrated by a long-term reproduction study in which Japanese quail were fed diet-incorporated chlorophacinone.

2.8.4.4.1 Primary poisoning

2.8.4.4.1.1 In and around buildings

The more direct the delivery of bait containing chlorophacinone to the target animals and the faster their consumption, the shorter the eradication campaign and ultimately the smaller the opportunity for non-target species to discover and ingest the bait. The secured bait points selected for deployment of bait in and around buildings are therefore placed where they are most likely to be encountered exclusively by the target organisms (*e.g*. on habitual rat-runs), thus maximising exposure of the target rodents and minimising unintended exposure of other non-target vertebrates. According to recommended practice, baiting campaigns with anticoagulant rodenticides continue until uptake monitoring indicates that eradication of the target rodent population has been achieved, at which point all remaining bait is retrieved and destroyed or securely disposed of. Elimination of residual bait in this way has two benefits: firstly it removes the potential for unintended exposure of non-target animals in the absence of competition from rats and mice, and secondly it reduces the likelihood of resistance (*i.e*. immunity to a particular active substance) developing among the target rodents. Knowledge of the site in which the control campaign is to be conducted also entails taking into account the presence of or possible access by non-target animals and selecting appropriate baits and degrees of bait point protection that minimise the potential for unintended exposure to occur.

▪ Primary poisoning - Short-term exposure - Qualitative assessment

To estimate the exposure to non-target vertebrates, it is assumed in the first instance that a quantity of bait will be eaten on a single occasion to satisfy a whole day's food intake requirement. As a tier 1, the actual assessment is normally based on a comparison of the (predicted) concentration of the chemical in the food (PEC_{oral}) and the (predicted) no-effect concentration for oral intake for the non-target organisms ($PNEC_{oral}$).

According to EUBEES 2 the worst case may be considered as a portion of 600 g bait as the normal upper limit for what is available to non-target animals. Thus the concentration of the rodenticide in the food of a non-target organism (PEC_{oral}) is the concentration of the active substance in the rodenticide bait to be taken up by the non-target animal 600 g at maximum in one daily meal.
The worst case is PECoral 50 mg as /kg of product (chlorophacinone present at 0.005% w:w in the product) and is used in the risk assessment.

Table 2.8.4.4.1.1.1: Quantities of chlorophacinone in grain baits potentially accessible to non-target vertebrates following deployment at secured bait points in and around buildings

Maximum size and maximum number per bait point	Maximum weight of chlorophacinone per bait point (mg a.s)	Proportion of bait point contents accessible (%)	chlorophacinone potentially (maximum) ingested by non-target vertebrates (mg a.s.) quantity	Concentration in food (mg a.s/kg food)
600 g (rat control)	30	100	30	50

The maximum value of concentration in food is the concentration of the substance in the product, 50 mg a.s/kg food. This value will be used in tier 1 considering that it represents all the species with a food consumption < 600 g per day. Additional estimations of doses for different species are presented below.

First tier: worst case scenario. For small non-target mammals and birds it is assumed that exposure to the full amount of chlorophacinone at secured bait points over a period of days will result in death. Exposure to an amount less than the full dosage placed at secured bait points may cause significant harm to small non-target animals. Domestic animals may accidentally ingest parts of grain baits discarded outside the secured bait points. The body weights, daily food intakes and estimates of chlorophacinone ingestion, based on sufficient bait grains being accessible to satisfy a day's food intake requirement, are presented below for a range of non-target mammals and birds based on the equation:

ETE = (FIR/BW) * C * AV * PT * PD (mg chlorophacinone/kg bw/day),

where ETE is the estimated theoretical exposure to the active substance, FIR is the non-target mammal food intake (fresh weight), BW is mammal bodyweight, C is the concentration of active substance in the fresh diet (grain baits), AV is the avoidance factor (default 1.0 = no avoidance), PT is the fraction of diet obtained in the treated area (default 1.0) and PD is the fraction of food type in the diet (default 1.0), first tier (worst case).

In the **second tier (realistic worst case)** AV = 0.9, PT = 0.8 and PD =1.

As it is mentioned in the EUBEES 2 guideline, the tier 1 can be used for both short and long-term exposure. The document suggests the use of the PNEC as toxicity endpoint. The exposure characterization is calculated below:

Table 2.8.4.4.1.1.2: Primary poisoning to mammals – Short term exposure - Qualitative assessment. Expected content of the active substance chlorophacinone in non-target animals (mammals) in the worst case situation, following the EUBEES-ESD (concentration of a.s. in rodenticide bait 0.0050%).

Organism	Species	Body weight (g)	Daily mean food intake (g)	Bait consumption (g product)	Estimated daily uptake of chlorophacinone, ETE (mg a.s/kg bw)	
					First tier*	Second tier*
Dog	*Canis familiaris*	10 000	-*	600.0	3.0	2.2
Pig	*Sus scrofa*	80 000	-*	600.0	0.4	0.3
Pig, young	*Sus scrofa*	25 000	-*	600.0	1.2	0.9
* Not stated in the EUBEES-ESD; simplistically, a maximum bait consumption of 600 g is assumed in rodenticide bait 0.005% .						

*First tier AV=1 PT=1; Second tier AV=0.9, PT=0.8 corrected for a maximum ingestion of 600 g bait.

Table 2.8.4.4.1.1.3: Primary poisoning to birds – Short term exposure - Qualitative assessment. Expected content of the active substance chlorophacinone in non-target animals (birds) in the worst case situation, following the EUBEES-ESD (concentration of a.s. in rodenticide bait 0.0050%).

Organism	Species	Body weight (g)	Daily mean food intake (g/d)	Bait consumption (g product)	First tier*		Second tier*	
					mg a.s/kg bw (ETE**)	mg a.s/kg food (PEC)	mg a.s/kg bw (ETE**)	mg a.s/kg food (PEC)
Tree sparrow	*Passer montanus*	22	7.6	7.6	17.3	50	12.4	36
Chaffinch	*Fringilla coelebs*	21.4	6.42	6.42	15.0	50	10.8	36
Wood pigeon	*Columba palumbus*	490	53.1	53.1	5.4	50	3.9	36
Pheasant	*Phasianus colchicus*	953	102.7	102.7	5.4	50	3.9	36

*First tier AV, PT and PD =1; Second tier AV=0.9, PT=0.8 and PD=1.
** Estimated daily uptake of chlorophacinone (ETE)

▪ Primary poisoning - Long-term exposure - Tier 1

As it is mentioned in the EUBEES 2 guideline, the tier 1 can be used for both short and long-term exposure. The document suggests the use of the PNEC as toxicity endpoint.

Table 2.8.4.4.1.1.4: Tier 1 of primary poisoning to mammals. Long-term risk characterization (chlorophacinone concentration 0.005%).

Organism	Maximum oral daily intake (mg a.s/kg bw) ETE	Maximum oral daily intake $PEC_{oral\ mammal}$ (mg a.s/kg food)**
Dog (10 kg)	3	50
Pig (80 kg)	0.4	50
Pig, young (25 kg)	1.2	50

* It is considered that the use of a PNEC food from a gavage rat study for assessing dogs and pigs without consideration of differences in food intake ratios should be taken with precaution, but the proposal for expressing the PNEC as dose was not accepted by the TM.
** PEC_{oral} for mammals has been based on the concentration of chlorophacinone in the product 0.005% assuming that the product represents 100% of the diet of the animal.

Table 2.8.4.4.1.1.5: Tier 1 of primary poisoning to birds. Long-term risk characterization (chlorophacinone concentration 0.005%)

Organism	Maximum oral daily intake (mg a.s/kg food) PEC_{oral}
Tree sparrow (22 g)	3 947
Chaffinch (21.4 g)	4 673
Wood pigeon (490 g)	565
Pheasant (953 g)	288

▪ Primary poisoning - Long-term exposure - Tier 2

Table 2.8.4.4.1.1.6: Tier 2. Long-term risk characterization for different primary poisoning scenarios to mammals (chlorophacinone concentration 0.005%)

Exposure scenario (species, $ENEL_{mammal}$)	ETE (mg a.s/kg bw)	
	First tier	Second tier
Dog (0.00017-0.00006 mg a.s/kg bw)	3.0	2.2
Pig (0.00017-0.00006 mg a.s/kg bw)	0.4	0.3
Pig, young (0.00017-0.00006 mg a.s/kg bw)	1.2	0.9

*First tier (worst case) AV, PT and PD = 1; Second tier (realistic worst case) AV = 0.9, PT = 0.8 and PD =1.

Primary poisoning to birds. Tier 2. Long-term exposure

Table 2.8.4.4.1.1.7:Tier 2. Primary poisoning. Expected content of the active substance chlorophacinone in non-target animals (birds) in the worst case situation (chlorophacinone concentration 0.005%).

Organism	**Species**	**Body weight (g)**	**Daily mean food intake (g/d)**	**Bait consumption**	**Estimated daily uptake of chlorophacinone, ETE (mg a.s/kg bw)**	
					First tier*	**Second tier***
Tree sparrow	*Passer montanus*	22	7.6	7.6	17.3	12.4
Chaffinch	*Fringilla coelebs*	21.4	6.42	6.42	15.0	10.8
Wood pigeon	*Columba palumbus*	490	53.1	53.1	5.4	3.9
Pheasant	*Phasianus colchicus*	953	102.7	102.7	5.4	3.9

*First tier (worst case) AV, PT and PD = 1; Second tier (realistic worst case) AV = 0.9, PT = 0.8 and PD =1.

Table 2.8.4.4.1.1.8:Tier 2. Long-term risk characterization for different primary poisoning scenarios to birds (chlorophacinone concentration 0.005%).

Exposure scenario species	**PEC (mg a.s/kg food) Realistic worst case**	
	First tier*	**Second tier***

Tree sparrow (22 g)	50	36
Chaffinch (21.4 g)	50	36
Wood pigeon (490 g)	50	36
Pheasant (953 g)	50	36

*First tier (worst case) AV, PT and PD = 1; Second tier (realistic worst case) AV = 0.9, PT = 0.8 and PD =1.

2.8.4.4.1.2 Open areas

Grain baits containing chlorophacinone are deployed in open areas to control populations of rodents. In this application, 3 × 30 g grains are placed into the openings of a tunnel network actively occupied by the target animals. The openings selected for baiting are closed after application, so that access to the bait is restricted to from within the tunnel system. Two applications over the course of six days are considered typical.
The primary poisoning risks to birds and mammals from ingestion of grain baits are assumed to be very low in open areas because delivery to the target animals is direct, the bait is not visible from above ground when the tunnel openings have been covered over and because the target rodents are unlikely to move pieces of grain bait from protection underground to places where they may become accessible to non-target birds and mammals.
The situation in the open area scenarios is basically similar to what has been mentioned for commensal rodents above in the In and around buildings scenario.

2.8.4.4.1.3 Waste Dumps

Grain baits contained in sachets, are deployed at waste-dumps and land-fill sites to control populations of rats. EUBEES 2 suggests a worst-case scenario in the event of an infestation outbreak that entails 40 kg of grains protected inside bait boxes and distributed over an area of 1 ha, with a total of seven such applications per year.
The primary poisoning risks to birds and mammals from ingestion of grain baits containing chlorophacinone are assumed to be similar to those indicated above for uses in and around buildings. Although the grain baits on waste dumps will initially be deployed in plastic sachets, it is possible that pieces of bait will be dropped following uptake of the bait by target rodents, in places where they may become accessible to non-target birds and mammals.

2.8.4.4.2 Secondary poisoning

2.8.4.4.2.1 In and around buildings

<u>Secondary poisoning - Short-term exposure - Qualitative assessment</u>

Rodents targeted by indoor and outdoor baiting campaigns are likely to roam outdoors and within the hunting ranges of predatory birds and mammals. Target animals that succumb to the effects of anticoagulant rodenticides and die whilst foraging outdoors may be found and ingested by scavenging vertebrates. A potential for secondary poisoning of birds and mammals therefore exists, even (though to a lesser extent) on occasions when the deployment of baits containing chlorophacinone is confined to the interiors of buildings.

EUBEES 2 cites three published reports of cage and enclosure studies in which the authors observed behavioural changes in poisoned rodents that would appear to increase their susceptibility to predation during daytime and also the likelihood that fatal haemorrhage would occur while the

rodents were away from shelter, leaving their carcasses exposed to scavengers[25]. The notifier adds the following information:

On the other hand, these predictions are contradicted by reports of observations made before, during and after anticoagulant baiting programmes conducted in and around farm buildings, where carcasses found by systematic searches were predominantly either indoors or concealed beneath cover (*e.g.* under haystacks)[26]. Bodies representing only 4% of an estimated initial rat population were found away from cover in one study and (in the absence of evidence of further activity) the majority of the remaining, unrecovered population was assumed to have died underground in a system of burrows.

It was considered in the inclusion dossier that a 4% of the rat population in the surface available to the non-target organism can mean a significant quantity of active substance implying risk for secondary poisoning.

In accordance with EUBEES 2 guidance, the following assessment of secondary poisoning takes into account the levels of chlorophacinone residues in target rodents, based on its concentration in baits, feeding (chlorophacinone intake) and excretion (chlorophacinone elimination) rates of target rodents, as well as the period over which the bait is eaten before the effects of poisoning inhibit further feeding. These combined factors form the basis of exposure to predators and scavengers upon which to assess risk.

The chlorophacinone residue concentration in rodents is based on the following equation:

$$EC_n = \sum_{n=1}^{n-1} ETE * (1 - EL)^n$$

- where EC_n is the estimated residue concentration in the rodent on day n, ETE is the estimated theoretical exposure as defined above for primary poisoning for mammals and EL is the fraction of residue eliminated from the target rodent per day.

The ETE values for rodents (mice and rats) are based on three theoretical levels of ingestion of baits constituting 100%, 50% and 20% of the daily food intake (to allow for various intakes of alternative foods), a FIR/kg bw of 0.1 for rats and mice and a concentration of chlorophacinone in baits equal to 50 mg/kg. The ETE values are therefore 5.0, 2.5, 1.00 mg chlorophacinone/kg bw for levels of bait consumption equivalent to 100%, 50% and 20% of daily food intake, respectively.

The default rate of elimination of residues from the bodies of target rodents is 30% per day (faecal route only). The elimination of residues has been measured from a pair of male rats fed with approximately 5.0 mg chlorophacinone/kg bw. Severe haemorrhaging occurred and the test rats eventually died. Significant metabolites of chlorophacinone were identified. The default daily elimination rate of 30% for anticoagulant rodenticides prescribed by EUBEES 2 is in general in accordance with the mean values measured for chlorophacinone, which averaged 33.5% over the first three days and ranged from 37.6% for day 1 to 52.8% for day 2.

[25] Cox, P. & R.H. Smith (1992). Rodenticide ecotoxicology: Prelethal effects of anticoagulants on rat behaviour. In *Proc. 15th Vertebrate Pest Conf.* (Eds.J.E. Borecco& R.E. Marsh). Published at Univ. of Calif., Davis, Calif, p.165-170.
Gemmeke, H. (1998). Versuche mit Antikoagulantien zur Abschätzung des Vergiftungsrisikos bei Beutegreifern. Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft 245, 401.
Saucy, F., A. Meylan& R. Poitry (2001). Lessons from 18 years of use of anticoagulants against fossorial *Arvicola terresris* in Switzerland. In *Advances in vertebrate pest management II*. (Eds. H.-J. Pelz, D.P. Cowan & C.J. Feare), Filander Verlag, Fürth, p. 71-90.

[26] Harrison, E.G., Porter, A.J. and Forbes, S. (1988). Development of methods to assess the hazards of a rodenticide to non-target vertebrates. Proceedings of the British Crop Protection Symposium.
Fenn, M.G.P., Tew, T.E. and MacDonald, D.W. (1987). Rat movements and control on an Oxfordshire farm. *J. Zoology, London.* **213**, 745-749.

Table 2.8.4.4.2.1.1: Elimination of chlorophacinone residues (^{14}C-equivalents) from male rats

Sampling time (days)	Radioactivity excreted (mean % of applied, estimated dose approximately 5.0 mg/kg bw[1])			
	Urine	Faeces	Volatiles	Total
1	0.383	37.19	0.025	37.6
2	0.241	52.54	0.013	52.8
3	0.082	10.08	0.004	10.2
4	0.052	1.8	0.006	1.9
Cumulative 3 day total	0.706	99.81	0.042	100.6
Cumulative 4 day total	0.758	101.61	0.048	102.4
[1] Based on individual doses of 1.43 and 1.28 mg ^{14}C-chlorophacinone per animal, individual bw not stated, range 200 to 250 g.				

The residue levels are also based on an assumption that ingestion of chlorophacinone in baits occurs consistently during the first five days of baiting and that feeding (including bait ingestion) ceases on day 6, followed by death on day 7. However, the time to death under more realistic conditions may differ from that observed in the laboratory if the target rodents have unrestricted access to alternative food(s). EUBEES 2 considers three levels of bait consumption by target rodents, expressed in terms of bait ingestion as a percentage of total daily food intake. A level of 20% is regarded as the minimum for an effective bait formulated to appeal to target rodents, whilst 100% represents the realistic worst-case view. In the presence of other, competing food sources (presumed to be present to allow a population of target rodents to become established), an intake of around 50% may be more likely.

The equation ETE = (FIR/BW)·C·AV·PT·PD (mg kg^{-1} bw/d) for primary poisoning can be used for calculating the amount of active substance being consumed by the target rodent. EC is the estimated residue concentration in the rat. FIR/BW = 0.1 as default value; it is assumed that rats eat 10% their own weight.

20% bait consumption (normal case). Total daily consumption where EC_n is the estimated residue concentration on day "n" before meal (minimun):
The principle in the calculations is for the first 5 days that the animal eats the same daily amount and eliminates 30% of its content of residues. As anticoagulant rodenticides are eliminated from the body mainly through faeces, a reasonable default value for elimination is 30% as a default value per day. Although no resistant rodents were detected, it will be included in this report for the sake of completeness.

Regarding a control operation against normal susceptible rodents, it is seen that the highest concentration of active substance is found in rodents that have just taken their last meal on the fifth day before they are going to die. The realistic worst case is considered best described when the target rodent has consumed an amount of rodenticide making up 100% of its daily food intake. (mg a.s./kg rat bw = mg a.s./ kg food for birds and mammals as predators organisms).

The ETE is the amount of active substance being consumed by the target rodent.

ETE = (FIR/BW)·C·AV·PT·PD = 0.1 x 50 x 1 x 1 x 0.2 = 1 mg a.s./kg rat bw/d = mg a.s/kg food/d
$EC_n = \Sigma^{n-1}{}_{n=1}$ ETE $(1\text{-EI})^n$
EC_1 = ETE (1-EI) = 1(1-0) = 1.0 mg a.s./kg rat bw after first meal
EC_2 = (EC_1 + ETE) (1 - EI) = (1+0) (1-0.3) = 0.7 mg a.s./kg rat bw before meal
EC_3 = (EC_2 + ETE) (1 – EI) = (0.7+1) 0.7 = 1.2 mg a.s./kg rat bw before meal
EC_4 = (EC_3 + ETE) (1 – EI) = (1.2+1) 0.7 = 1.5 mg a.s./kg rat bw before meal

EC_5 = (EC_4 + ETE) (1 – EI) = (1.5+1) 0.7 = 1.8 mg a.s./kg rat bw before last meal
EC_5 = (EC_4 + ETE) (1 – EI) = (1.8+1) 0.7+1 = 2.8 mg a.s./kg rat bw after last meal
EC_6 = (EC_5 + ETE) (1 – EI) = (3.0+0) 0.7 =2.1 mg a.s./kg rat bw no feeding
EC_7 = (EC_6 + ETE) (1 – EI) = (2.1+0) 0.7 =1.5 mg a.s./kg rat bw no feeding

In case of resistance to the rodenticide:
EC_{14} = (EC_{13} + ETE) = 3.3 mg a.s./kg rat bw after last meal.

50% bait consumption (intermediate situation):
ETE = (FIR/BW)·C·AV·PT·PD = 0.1 x 50 x 1 x 1 x 0.5 = 2.5 mg a.s./kg rat bw/d
$EC_n = \Sigma^{n-1}_{n=1}$ ETE $(1\text{-EI})^n$
EC_1 = ETE (1-EI) = 2.5 (1-0) = 2.5 mg a.s./kg rat bw after first meal
EC_2 = (EC_1 + ETE) (1 - EI) = (2.5+0) (1-0.3) = 1.8 mg a.s./kg rat bw before meal
EC_3 = (EC_2 + ETE) (1 – EI) = (1.8+2.5) 0.7 = 3.0 mg a.s./kg rat bw before meal
EC_4 = (EC_3 + ETE) (1 – EI) = (3.0+2.5) 0.7 = 3.8 mg a.s./kg rat bw before meal
EC_5 = (EC_4 + ETE) (1 – EI) = (3.8+2.5) 0.7 = 4.4 mg a.s./kg rat bw before last meal
EC_5 = (EC_4 + ETE) (1 – EI) = (3.8+2.5) 0.7+2.5 = 6.9 mg a.s./kg rat bw after last meal
EC_6 = (EC_5 + ETE) (1 – EI) = (6.9+0) 0.7 =4.8 mg a.s./kg rat bw no feeding
EC_7 = (EC_6 + ETE) (1 – EI) = (4.8+0) 0.7 =3.4 mg a.s./kg rat bw no feeding

In case of resistance to the rodenticide:
EC_{14} = (EC_{14} + ETE) = 8.3 mg a.s./kg rat bw after last meal.

100% bait consumption (realistic worst case):
ETE = (FIR/BW)·C·AV·PT·PD = 0.1 x 50 x 1 x 1 x 1.0 = 5 mg a.s./kg rat bw/d
$EC_n = \Sigma^{n-1}_{n=1}$ ETE $(1\text{-EI})^n$
EC_1 = ETE (1-EI) = 5 (1-0) = 5 mg a.s./kg rat bw after first meal
EC_2 = (EC_1 + ETE) (1 - EI) = (5+0) (1-0.3) = 3.5 mg a.s./kg rat bw before meal
EC_3 = (EC_2 + ETE) (1 – EI) = (3.5+5) 0.7 = 6.0 mg a.s./kg rat bw before meal
EC_4 = (EC_3 + ETE) (1 – EI) = (6.0+5) 0.7 = 7.7 mg a.s./kg rat bw before meal
EC_5 = (EC_4 + ETE) (1 – EI) = (7.7+5) 0.7 = 8.9 mg a.s./kg rat bw before last meal
EC_5 = (EC_4 + ETE) (1 – EI) = (7.7+5) 0.7+5 = 13.9 mg a.s./kg rat bw after the last meal
EC_6 = (EC_5 + ETE) (1 – EI) = (13.9+0) 0.7 =9.7 mg a.s./kg rat bw no feeding
EC_7 = (EC_6 + ETE) (1 – EI) = (9.7+0) 0.7 =6.8 mg a.s./kg rat bw no feeding

In case of resistance to the rodenticide:
EC_{14} = (EC_{14} + ETE) = 16.6 mg a.s./kg rat bw after last meal.

Table 2.8.4.4.2.1.2: Residues of chlorophacinone in target rodents from the ingestion of baits at different times during a control campaign, calculated according to EUBEES 2. Used in the secondary poisoning short-term (one single dose) exposure of the predator.

Time A normal non-resistant target rodent stops eating on day 5	**EC_n Residues of chlorophacinone in target rodent (mg/kg rat bw = mg a.s/kg food)**		
	20% bait consumption (normal situation)	**50% bait consumption (intermediate situation)**	**100% bait consumption (realistic worst case)**
No resistance situation			
EC_1 Day 1, before first meal	1.0	2.5	5.0

EC_2 Day 2 before new meal	0.7	1.8	3.5
EC_3 Day 3 before new meal	1.2	3.0	6.0
EC_4 Day 4 before new meal	1.5	3.8	7.7
EC_5 Day 5 before last meal	1.8	4.4	8.9
EC_5+ETE **Day 5 after last meal without elimination**	**2.8**	**6.9**	**13.9**
EC_6 Day 6 no feeding	2.1	4.8	9.7
EC_7 Day 7 (mean time to death)*	1.5	3.4	6.8
Resistance situation			
EC_{14} Day 14 after last meal just in case of resistance**	3.3	8.3	16.6

* The feeding period has been set to a default value of 5 days until the onset of symptoms after which the rodent eats nothing until its death.
** no resistance has been detected for chlorophacinone.

Calculated residue patterns suggest that levels increase following each daily intake until day 5 after last meal before they are going to die, after which the rodents are assumed to eat no more baits, but to continue to excrete residues at approximately 30% per day, resulting in a reduction of residues by approximately half between the last intake on day 5 and death on day 7.

It is assumed that the rodents have fed entirely on rodenticide (i.e. 100%, PD =1) as a realistic worst case scenario. In the TGD it is assumed that the non-target animals consume 50% of their daily intake on poisoned animals but it will be assumed a 100% as a realistic worst case since a small rat is more than 50% of some predators' diet and a moderate sized rat would be over 100% therefore, in the case of a short-term exposure the fraction of poisoned rodents in predator's diet might be assumed to be 1 as a realistic worst case at least for the smaller predators (e.g. all except fox; in the case of foxes in a short-term exposure situation, the fraction of poisoned rodents in their diet might be below 1) and 50% of the predator's diet will be rats for long-term exposures. Anyhow, for the sake of completeness all combinations will be done.

Thus, these calculations can be used for a first tier realistic worst case scenario. The $PEC_{oral\ predator}$ is estimated to be 5 days after the last meal (without elimination).

Table 2.8.4.4.2.1.3: Tier 1. Secondary poisoning. $PEC_{oral\ predator}$. Short-term exposure (one single dose)

	$PEC_{oral,\ predator}$ (mg a.s/kg rat-bw = mg a.s/kg food)		
	20% bait consumption	50% bait consumption (normal situation)	100% bait consumption (realistic worst case)
Day 5 after last meal No resistance situation	2.8	6.9	13.9
Day 14 after last meal Resistance situation	3.3	8.3	16.6

Table 2.8.4.4.2.1.4:Tier 1 for secondary poisoning for non-target mammals. Short-term exposure (one single dose).

Bait consumption	$ETE_{predator}$ (mg a.s./kg predator bw)	$PEC_{oral\ predator}$ (mg a.s./kg food)
Based on residues in the rat after 5 days of ingestion after last meal. No resistance situation		
20% normal situation Fox *Vulpes vulpes* (5,700 g; 520.2 g food (rat in this case)/d DFI)	0.2*	2.8
50% intermediate	0.6*	6.9
100% realistic worst case (not for foxes)***	1.3 *	13.9
20% Polecat *Mustela putorius* (689 g; 130.9 g/d DFI)	0.5*	2.8
50%	1.3*	6.9
100%	2.6*	13.9
20% Stoat *Mustela erminea* (205 g; 55.7 g/d DFI)	0.8*	2.8
50%	1.9*	6.9
100%	3.8*	13.9
20% Weasel *Mustela nivalis* (63 g; 24.7 g/d DFI)	1.1*	2.8
50%	2.7*	6.9
100%	5.4*	13.9
Based on residues in rodents after 14 days of ingestion after last meal. Resistance situation		
20% Fox	0.3**	3.3
50%	0.8**	8.3
100% (not for foxes)***	1.5**	16.6
20% Polecat	0.6**	3.3
50%	1.6**	8.3
100%	3.2**	16.6
20% Stoat	0.9**	3.3
50%	2.2**	8.3
100%	4.5**	16.6
20% Weasel	1.3**	3.3
50%	3.2**	8.3
100%	6.5**	16.6

* Based on a $PEC_{oral\ predator}$ of 2.8, 6.9 and 13.9 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively
** Based on a PECoral predator of 3.3, 8.3 and 16.6 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively
DFI = Daily Food Intake.
*** In the case of foxes, in a short-term exposure situation, the fraction of poisoned rodents in their diet might be below 1

Table 2.8.4.4.2.1.5: Tier 1 for secondary poisoning for non-target birds. Short-term exposure (one single dose)

Bait consumption	ETE_{birds} (mg a.s/kg predator bw)	$PEC_{oral\ birds}$ (mg a.s/kg food)
Based on residues in the rat after 5 days of ingestion after last meal. No resistance situation		
20% Barn owl *Tyto alba* (294 g bw; 72.9 g food (rat in this case, Daily Food Intake)	0.7*	2.8
50%	1.7*	6.9

100%	3.4*	13.9
20% Kestrel *Falco tinnunculus* (209 g bw; 78.7 g DFI)	1.0*	2.8
50%	2.6*	6.9
100%	5.2*	13.9
20% Little owl *Athene noctua* (164 g bw;46.4 g DFI)	0.8*	2.8
50%	2.0*	6.9
100%	3.9*	13.9
20% Tawny owl *Strix aluco* (426 g bw; 97.1 g DFI)	0.6*	2.8
50%	1.6*	6.9
100%	3.2*	13.9
Based on residues in rodents after 14 days of ingestion after last meal. Resistance situation		
20% Barn owl	0.8**	3.3
50%	2.0**	8.3
100%	4.1**	16.6
20% Kestrel	1.2**	3.3
50%	3.1**	8.3
100%	6.2**	16.6
20% Little owl	0.9**	3.3
50%	2.3**	8.3
100%	4.7**	16.6
20% Tawny owl	0.8**	3.3
50%	1.9**	8.3
100%	3.8**	16.6

* Based on a $PEC_{oral\ predator}$ of 2.8, 6.9 and 13.9 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively
** Based on a $PEC_{oral\ predator}$ of 3.3, 8.3 and 16.6 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively
DFI = Daily Food Intake

Table 2.8.4.4.2.1.6: Tier 2 for secondary poisoning for non-target mammals containing chlorophacinone obtained from areas in and around buildings. Short-term exposure. Qualitative approach

Bait consumption	$ETE_{predator}$ (mg a.s./kg predator bw)
based on residues in the rat after 5 days of ingestion after last meal	
20% normal situation Fox *Vulpes vulpes* (5,700 g; 520.2 g food (rat in this case)/d DFI)	0.02*
50% intermediate	0.04*
100% realistic worst case (not for foxes)	0.08*
20% Polecat *Mustela putorius* (689 g; 130.9 g/d DFI)	0.04*
50%	0.09*
100%	0.18*
20% Stoat *Mustela erminea* (205 g; 55.7 g/d DFI)	0.05*
50%	0.12*
100%	0.25*
20% Weasel *Mustela nivalis* (63 g; 24.7 g/d DFI)	0.07*
50%	0.18*
100%	0.36*

* Based on a $PEC_{oral\ predator}$ of 0.19, 0.46 and 0.93 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

The lowest acute endpoint is for dog LD_{50} « 2 mg a.s/kg bw. All values are below the threshold of the acute endpoint (although the uncertainty in the test for dogs still remains since the endpoint value is expressed as much lower than 2 mg a.s/kg bw). The level of the risk is not clarified with this approach, as an ETE below the LD_{50} does not indicate the absence of unacceptable risk if the required margin of safety is not established.

Table 2.8.4.4.2.1.7: Tier 2 for secondary poisoning for non-target birds containing chlorophacinone obtained from areas in and around buildings. Short-term exposure. Qualitative approach

Bait consumption	ETE_{birds} (mg a.s./kg predator bw)
based on residues in the rat after 5 days of ingestion after last meal	
20% Barn owl *Tyto alba* (294 g bw; 72.9 g food (rat in this case, Daily Food Intake)	0.05*
50%	0.11*
100%	0.23*
20% Kestrel *Falco tinnunculus* (209 g bw; 78.7 g DFI)	0.07*
50%	0.17*
100%	0.35*
20% Little owl *Athene noctua* (164 g bw;46.4 g DFI)	0.05*
50%	0.30*
100%	0.61*
20% Tawny owl *Strix aluco* (426 g bw; 97.1 g DFI)	0.04*
50%	0.10*
100%	0.21*

* Based on a $PEC_{oral\ predator}$ of 0.19, 0.46 and 0.93 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

Secondary poisoning - Long-term exposure – Tier 1

Table 2.8.4.4.2.1.8: Tier 1 for secondary poisoning for non-target mammals. Long-term exposure

Bait consumption	$ETE_{predator}$ (mg a.s/kg bw)	$PEC_{oral\ predator}$ (mg a.s/kg food)
Based on residues in the rat after 5 days of ingestion after last meal. No resistance situation		
20% normal situation Fox (5,700 g; 520.2 g food (rat in this case/d DFI)	0.1*	1.4
50% intermediate	0.3*	3.4
100% realistic worst case	0.6*	7.0
20% Polecat (689 g; 130.9 g/d DFI)	0.3*	1.4
50%	0.7*	3.4
100%	1.3*	7.0
20% Stoat (205 g; 55.7 g/d DFI)	0.4*	1.4
50%	1.0*	3.4
100%	1.9*	7.0
20% Weasel (63 g; 24.7 g/d DFI)	0.5*	1.4

50%	1.4*	3.4
100%	2.7*	7.0
Based on residues in rodents after 14 days of ingestion after last meal. Resistance situation		
20% Fox	0.2**	1.7
50%	0.4**	4.2
100%	0.8**	8.3
20% Polecat	0.3**	1.7
50%	0.8**	4.2
100%	1.6**	8.3
20% Stoat	0.5**	1.7
50%	1.1**	4.2
100%	2.2**	8.3
20% Weasel	0.7**	1.7
50%	1.6**	4.2
100%	3.2**	8.3

* Based on a $PEC_{oral\ predator}$ of 1.4, 3.4 and 7.0 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

** Based on a PECoral predator of 1.7, 4.2 and 8.3 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

DFI = Daily Food Intake

Table 2.8.4.4.2.1.9: Tier 1 for secondary poisoning for non-target birds. Long-term exposure

Bait consumption	$PEC_{oral\ bird}$ (mg a.s./kg food)
Based on residues in the rat after 5 days of ingestion after last meal. No resistance situation	
20%	1.4
50%	3.4
100%	7.0
Based on residues in rodents after 14 days of ingestion after last meal. Resistance situation	
20%	1.7
50%	4.2
100%	8.3

* Based on a PEC_{oral} of 1.4, 3.4 and 7.0 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

** Based on a PEC_{oral} of 1.7, 4.2 and 8.3 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

Secondary poisoning - Long-term exposure – Tier 2

In the table below the various concentrations of chlorophacinone in target rodents on day 5 and day 7 have been lowered *pro rata* to reflect real, measured residues instead of the estimated values based on kinetics. This information comes from the simulated field testing of secondary poisoning of birds where the higher residues were measured in rat carcasses.

Table 2.8.4.4.2.1.10: Residues of chlorophacinone in target rodents from the ingestion of baits at different times during a control campaign, based on the maximum residue level measured in rats. Measured in homogenised whole-body tissues of rat carcasses. Used in the secondary poisoning short-term exposure (one single dose) of the predator.

Time	**Residues of chlorophacinone in target rodent (mg a.s./kg rat bw) $EC_{refined}$**		
	20% bait consumption	**50% bait consumption**	**100% bait consumption**
Day 5 after last meal[1]	**0.19**	**0.46**	**0.93**
Day 7 (mean time to	0.10	0.24	0.47

death)[2]			
[1] Based on 0.9272 mg/kg bw measured after 100% bait consumption for 5 days (see Doc. III-A 7.5.6-01); [2] Based on excretion of 30% per day and a reduction of approximately 50% between days 5 and 7.			

Due to the incidents occurred in Spain in February 2007, a group of experts from the INIA sampled the area and collected carcasses from common voles (*Microtus arvalis*) in order to analyse residues of chlorophacinone in their bodies. Chlorophacinone was extracted and the analysis were carried out with an HPLC-mass spectrometry. The Limit of Detection (LOD) was ≥ 20 ng/g wet weight and the Limit Of Quantification, LOQ, ≥ 30 ng/g wet weight. The concentrations found varied from the LOD up to 0.5 µg/g bw. Considering a mean weight of 20-30 g and an uniform distribution of the substance in the whole organism, the maximum quantity of rodenticide per animal would be between 10 and 15 µg cpn. These results are in line with those described in the bibliography (Primus Th.M. *et al*. (2001)[27]).

This incident also offered indications, not confirmed, of secondary poisoning of mammals with levels clearly much lower than those used in the EUBEES 2 guideline and similar to the ones provided by the notifier.

Table 2.8.4.4.2.1.11: Residues of chlorophacinone in target rodents from the ingestion of baits at different times during a control campaign, based on the maximum residue level measured in rats. Used in the secondary poisoning long-term exposure of the predator.

Time	**Residues of chlorophacinone in target rodent (mg a.s./kg rat bw) $EC_{refined}$**		
	20% bait consumption	**50% bait consumption**	**100% bait consumption**
Day 5 after last meal[1]	**0.10**	**0.24**	**0.47**
Day 7 (mean time to death)[2]	0.05	0.12	0.23
[1] Based on 0.9272 mg/kg bw measured after 100% bait consumption for 5 days (see Doc. III-A 7.5.6-01); [2] Based on excretion of 30% per day and a reduction of approximately 50% between days 5 and 7.			

Table 2.8.4.4.2.1.12: Tier 2 for secondary poisoning for non-target mammals containing chlorophacinone obtained from areas in and around buildings. Long-term exposure

Bait consumption	$ETE_{predator}$ (mg a.s./kg predator bw)
based on residues in the rat after 5 days of ingestion after last meal	
20% normal situation Fox *Vulpes vulpes* (5,700 g; 520.2 g food (rat in this case)/d DFI)	0.01*
50% intermediate	0.02*
100% realistic worst case	0.04*
20% Polecat *Mustela putorius* (689 g; 130.9 g/d DFI)	0.02*
50%	0.04*

[27] Primus Th.M, Eisemann J.D., Matschke G.H. Ramey C., Johnston J.J (2001). Chlorophacinone residues in Rangeland rodents: An assessment of the potencial risk of secondary toxicity to scavengers. En: *Pesticides and Wildlife*. Editos: Johnstan J.J. ACS Symposium Series 771. American Chemical Society. Washintong DC. Pp. 164-180.

100%	0.08*
20% Stoat *Mustela erminea* (205 g; 55.7 g/d DFI)	0.02*
50%	0.06*
100%	0.12*
20% Weasel *Mustela nivalis* (63 g; 24.7 g/d DFI)	0.04*
50%	0.09*
100%	0.18*

* Based on a $PEC_{oral\ predator}$ of 0.10, 0.23 and 0.46 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively
DFI = Daily Food Intake

Table 2.8.4.4.2.1.13: Tier 2 for secondary poisoning for non-target birds containing chlorophacinone obtained from areas in and around buildings. Long-term exposure

Bait consumption	$PEC_{oral\ bird}$ (mg a.s./kg food)
based on residues in the rat after 5 days of ingestion after last meal	
20%	0.10
50%	0.23
100%	0.46

2.8.4.4.2.2 Open areas

Secondary poisoning hazard may occur in the open area scenario. Predators among mammals and birds may occur in the immediate vicinity of buildings, e.g. parks and gardens or further away. When moving around the rats may be caught by raptors and scavengers may find dead rats. The secondary poisoning risks to birds and mammals following the use of baits containing chlorophacinone in open areas are adequately quantified for uses in and around buildings as above.

2.8.4.4.2.3 Waste dump

The secondary poisoning risks to birds and mammals following the use of baits containing chlorophacinone in waste dumps are adequately quantified for uses in and around buildings as above.

2.8.5 Risk characterisation for the environment

Risk characterization for the environment is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC) according to the guidance in Technical guidance document (TGD, 2003) and 'Emission scenario document for biocides used as rodenticides' (Larsen, 2003, hereafter ESD).
The environmental risk characterization has been carried out for chlorophacinone.

2.8.5.1 Aquatic compartment (including water, sediment and STP)

2.8.5.1.1 In and around building

The exposure of surface water is not considered relevant in the EUBEES 2 ESD for rodenticides. Chlorophacinone is not expected to occur in the aquatic compartment to any significant extent (EUBEES 2) following the use of grain baits in and around buildings. Therefore, PEC values for

chlorophacinone in surface water and sediment are assumed to be negligible and have not been further considered.

2.8.5.1.2 Open areas

The exposure of surface water arising from the use of CAID GRAIN' TECH bait in open areas is not expected to be significant or widespread. Therefore, estimates of chlorophacinone concentrations in surface water have not been calculated and aquatic PEC/PNEC quotients are not presented. Since the scope for exposure is negligible, the risks presented to aquatic biota by chlorophacinone are expected to be very low. No further assessment of risk is necessary.

2.8.5.1.3 Waste dump

The exposure of surface water arising from the use of CAID GRAIN' TECH bait is not expected to be significant or widespread. Therefore, estimates of chlorophacinone concentrations in surface water have not been calculated and aquatic PEC/PNEC quotients are not presented. Since the scope for exposure is negligible, the risks presented to aquatic biota by chlorophacinone deployed in waste dumps are expected to be very low. No further assessment of risk is necessary.

2.8.5.2 Atmospheric compartment

Chlorophacinone exhibits a negligible vapour pressure of 4.76×10^{-4} Pa at ambient temperature. The estimated half-life for the hydroxyl reaction in air is 14.3 hours and Henry's law constant is 0.013725 $Pa.m^3.mol^{-1}$ (based on a water solubility of 13.0 mg a.s/l). Therefore chlorophacinone is not expected to volatilise to air in significant quantities. The use pattern and means by which chlorophacinone is deployed in grain baits, coupled with its low volatility, ensure that exposure to non-target biota via the atmosphere is highly unlikely. No further assessment of risk is necessary.

2.8.5.3 Terrestrial compartment (Soil and groundwater)

Soil exposure occurs both through a combination of direct and/or indirect releases from the use of CAID GRAIN' TECH bait in the scenario "in and around buildings", "open area" and "waste dumps".

2.8.5.3.1 In and around building

Exposure of the terrestrial compartment (soil) will occur when CAID GRAIN' TECH bait is deployed outdoors.

Realistic worst case and typical case predicted soil concentrations (PECs) have been calculated for the use scenario in and around buildings, for application in rats and mice control campaign. The resulting PEC/PNEC ratios for soil are summarized in the Table below for the worst case concentrations in soil, cumulating the direct and indirect emissions :

Table 2.8.4.4.2.3: PECsoil/PNECsoil for soil-dwelling invertebrates exposed to chlorophacinone following outdoor use of grain baits around buildings

Baiting scenario (EUBEES 2)	Maximum PECsoil (mg chlorophacinone /kg wwt soil)	PNECsoil (mg chlorophacinone/kgwwt soil)	PEC/PNEC ratio
Rats			
Realistic worst-case	3.86E-02	0.3	0.129
Typical	1.16E-02	0.3	0.039
Mice			
Realistic worst-case	2.83E-02	0.3	0.094

Typical	8.48E-03	0.3	0.028

The PEC/PNEC ratios shown above are less than 1.0 and indicate that there are no unacceptable risks to the terrestrial compartment when the product CAID GRAIN' TECH is used in and around building.

Table 2.8.4.4.2.3: PECgroundwater based the mean concentration in soil - - outdoor use of grain baits around buildings

Baiting scenario (EUBEES 2)	PECgroundwater (µg chlorophacinone/ L porewater)	Threshold value in groundwater (µg chlorophacinone /L)	Conclusion
Rats			
Realistic worst-case	2.19E-02	0.1	**Acceptable**
Typical	6.56E-03	0.1	**Acceptable**
Mice			
Realistic worst-case	4.37E-02	0.1	**Acceptable**
Typical	1.31E-02	0.1	**Acceptable**

Considering the mean concentration in soil leading to emission to groundwater, the PEC for porewater are below the acceptable threshold value.

Therefore, risk for groundwater is acceptable for use in and around building proposed for CAID GRAIN' TECH.

2.8.5.3.2 Open areas

Exposure of the terrestrial compartment (soil) will occur when CAID GRAIN' TECH bait is applied in open areas by inserting inside the openings of the tunnels of the target rodents.

Predicted soil concentrations (PECs) have been calculated for the use scenario in open areas, for application in rats and mice control campaign. The resulting PEC/PNEC ratios for the soil are summarized in the Table below:

Table 2.8.4.4.2.3: Risk characterization in soil in Open areas for CAID GRAIN' TECH

Baiting scenario (EUBEES 2)	PEC_{soil} (mg cpn/kg wwt)	$PNEC_{soil}$ (mg cpn/kg wwt)	PEC/PNEC
Worst-case - Rats	0.346	0.30	**1.153**
Worst-case - Mice	0.173	0.30	0.577

The PEC/PNEC ratio for rats is above 1.0 and indicate that there is unacceptable risks to the terrestrial compartment when the product CAID GRAIN' TECH is used in the tunnels of open areas. However, risk for terrestrial compartment is below 1.0 and can be considered as acceptable for mice.

The PEC/PNEC ratios calculated indicate a marginal risk based on the PEC that represents a localised "hotspot" of contamination near the entrance of each baited tunnel. However, CAID GRAIN' TECH is specifically formulated to maintain bait integrity in damp environments, the extent of release of chlorophacinone into the floor of the tunnel is likely to be considerably less than the 25% suggested in EUBEES 2. Moreover, as the target rodents will eat and translocate portions of edible baits, and since much of the active substance will subsequently be excreted over a wide area outside the tunnel network, soil concentrations elsewhere will be considerably lower and will not be of concern.

According to the EUBEES 2 scenario, the use near the openings of the tunnels is covered by the assessment of the scenario "in and around buildings" with bait box.

No risk assessment has been carried out for groundwater contamination considering this type of use is applied in restricted area.

2.8.5.3.3 Waste dump

Exposure of the terrestrial compartment (soil) will occur when CAID GRAIN' TECH bait is deployed around the perimeter of waste-dumps and land-fill sites to control populations of rats and mice.
Detailed PNEC and PEC calculations are presented in the previous sections.Only local PECs are used since regional and continental releases are regarded to be negligible (ESD EUBEES 2003). No risk characterization for the manufacturing and formulation processes is conducted as the environmental exposure from these life-cycle steps is expected to be low.
Predicted soil concentrations (PECs) have been calculated for the use scenario in open areas, for application against rats and mice control campaign. The resulting PEC/PNEC ratios for the soil are summarized in the Table below:

Table 2.8.4.4.2.3: PECsoil/PNECsoil for soil-dwelling invertebrates exposed to chlorophacinone following use of grain baits in waste dumps and landfill sites

Baiting scenario	PECsoil (mg chlorophacinone /kg)	PNECsoil (mg chlorophacinone /kg)	PEC/PNEC ratio
Default parameters (EUBEES 2)[b]	0.0074	0.3	0.025
Label instructions	0.0424	0.3	0.141

The PEC/PNEC ratios shown above are less than 1.0 and indicate that there is no unacceptable risks to the terrestrial compartment when the product CAID GRAIN' TECH is used in waste dump.

Concentrations in porewater have been calculated for the application in waste dumps.

Table 2.8.4.4.2.3: Worst-case concentrations of chlorophacinone in porewater following baiting in waste dumps/landfills with grain baits considering the ESD parameter or the label instructions

Baiting scenario	maximum PECporewater (µg chlorophacinone/L porewater)	Threshold value for groundwater (µg/L)	risk characterization

Default parameters (EUBEES 2)[b]	2.69E-02	0.1	Acceptable
Label instructions	1.54E-01	0.1	Non acceptable

Table 2.8.4.4.2.3: Concentrations of chlorophacinone in porewater just after the 7th application considering degradation following baiting in waste dumps/landfills with grain baits (ESD parameter or the label instructions)

Baiting scenario	maximum PECporewater (µg chlorophacinone/L porewater)	Threshold value for groundwater (µg/L)	risk characterization
Default parameters (EUBEES 2)[b]	1.24E-02	0.1	Acceptable
Label instructions	7.11E-02	0.1	Acceptable

The concentrations of chlorophacinone in porewater are below the threshold value for groundwater when degradation is considered and indicate that there is no unacceptable risks to groundwater when the product CAID GRAIN' TECH is used in waste dump.

2.8.5.4 Non-compartmental specific effects relevant to the food chain

2.8.5.4.1 Primary poisoning

2.8.5.4.1.1 In and around buildings

Basically the same set of physiological processes is responsible for maintaining life for warm-blooded animals, i.e. mammals and birds. Therefore, the use of rodenticides meant for killing selected pest mammals has to be considered a general hazard to non-target mammals and birds as well.When anticoagulant rodenticides are applied according to label instructions (required by the authorities), the primary poisoning hazard may be considered as small. However, small non-target rodents and small, mostly granivorous, birds may be exposed because they can pass through the entrance hole of a bait station. Another exposure of non-target animals may arise when target animals carry bait away from e.g. baits stations.

Primary poisoning short-term exposure qualitative assessment

It is stated in the CAR of the active substance that regarding the qualitative assessment only a description of the toxicity of the substance compared to the possible single uptake is presented instead of carrying out a quantitative risk assessment. It is important to stress that this qualitative assessment is a simple comparison of the acute exposure situation with single dose LD_{50} values. The qualitative risk assessment is not intended to be used for risk characterisation; no $PNEC_{oral}$ shall be derived and hence no PEC/PNEC ratio can be established. This comparison should only give a first indication of the acute toxicity of the substance. This qualitative assessment is not intended to be used for the risk characterisation of primary and secondary poisoning of rodenticides and shall not be used for a comparative assessment.

Primary poisoning to mammals. Short-term exposure

Table 2.8.5.4.1.1.1: Primary poisoning to mammals - Qualitative assessment. Expected content of the active substance chlorophacinone in non-target animals (mammals) in the worst case situation, following the EUBEES-ESD (concentration of a.s. in rodenticide bait 0.0050%). Short-term exposure (single uptake. Acute effects)

Organism	Species	Body weight (g)	Daily mean food intake (g)	Bait consumption (g product)	Estimated daily uptake of chlorophacinone, ETE (mg a.s/kg bw)	
					First tier*	Second tier*
Dog	*Canis familiaris*	10 000	-*	600.0	**3.0**	**2.2**
Pig	*Sus scrofa*	80 000	-*	600.0	0.4	0.3
Pig, young	*Sus scrofa*	25 000	-*	600.0	1.2	0.9
* Not stated in the EUBEES-ESD; simplistically, a maximum bait consumption of 600 g is assumed in rodenticide bait 0.005% (based on maximum amount available rather than maximum daily intake values).						

*First tier (worst case) AV, PT and PD =1; Second tier (realistic worst case) AV=0.9, PT=0.8 and PD=1.

The lowest acute endpoint is for dog LD_{50} << 2 mg a.s/kg bw.
Making the comparison between the ETE and the acute endpoint, only dogs present a higher exposure than the ecotoxicological endpoint of LD_{50} << 2 mg a.s/kg bw. For the rest of the mammals the level of the risk not clarified with this approach, as an ETE below but close to the LD_{50} does not indicate the absence of unacceptable risk.

Primary poisoning to birds. Short-term exposure

Table 2.8.5.4.1.1.2: Primary poisoning to birds qualitative assessment. Expected content of the active substance chlorophacinone in non-target animals (birds) in the worst case situation, following the EUBEES-ESD (concentration of a.s. in rodenticide bait 0.0050%). Short-term exposure (single uptake. Acute effects).

Organism	Species	Body weight (g)	Daily mean food intake (g food/d)	Bait consumption (g product)	First tier*		Second tier*	
					ETE** mg a.s./kg bw	PEC mg a.s/kg food	ETE mg a.s/kg bw	PEC mg a.s/kg food
Tree sparrow	*Passer montanus*	22	7.6	7.6	17.3	50	12.4	36
Chaffinch	*Fringilla coelebs*	21.4	6.42	6.42	15.0	50	10.8	36
Wood pigeon	*Columba palumbus*	490	53.1	53.1	5.4	50	3.9	36
Pheasant	*Phasianus colchicus*	953	102.7	102.7	5.4	50	3.9	36

*First tier (worst case) AV, PT and PD =1; Second tier (realistic worst case) AV=0.9, PT=0.8 and PD=1.
**ETE, Estimated daily uptake of chlorophacinone

The lowest acute endpoint is for *C. virginianus* LD_{50} = 257 mg a.s/kg bw. All ETE are below this endpoint for birds. The level of the risk is not clarified with this approach, as an ETE below the LD_{50} does not indicate the absence of unacceptable risk if the required margin of safety is not established.

Conclusion: The qualitative approach for the acute situation confirms the potential risk of primary poisoning to dogs. The level of the risk is not clarified for all other species with this approach, as an ETE below the LD_{50} does not indicate the absence of unacceptable risk if the required margin of safety is not established.

▪ Primary poisoning long-term exposure

As it is mentioned in the EUBEES 2 guideline, the tier 1 can be used for both short and long-term exposure. The document suggests the use of the PNEC as toxicity endpoint.

Primary poisoning to mammals. Tier 1. Long-term exposure

Table 2.8.5.4.1.1.3: Tier 1 of primary poisoning to mammals. Long-term risk characterization (bait 0.005%)

Organism	**Maximum oral daily intake** (mg a.s/kg bw) **ETE**	**Maximum oral daily intake PEC_{oral} mammal (mg a.s/kg food)****	**$ENEL_{mammal}$** (mg a.s/kg bw)	**$PNEC_{mammal}$** (mg a.s/kg food)	**$ETE_l/ENEL_{mammal}$ Based on kg bw**	**$PEC_{oral}/PNEC_{mammal}$ Based on kg food**
Dog (10 kg)	3	**50**	0.00017-0.00006	**0.0011**	17 647-50 000	**45 454**
Pig (80 kg)	0.4	**50**	0.00017-0.00006	**0.0011**	2 352-6 667	**45 454**
Pig young (25 kg)	1.2	**50**	0.00017-0.00006	**0.0011**	7 559-20 000	**45 454**

** PEC_{oral} for mammals has been based on the concentration of cpn in the product 0.005% assuming that the product represents 100% of the diet of the animal.

All values are very high suggesting a potential high risk. However, it should be considered that the use of a long-term PNEC is not realistic, as it assumes that the same non-target mammal must ingest the bait every day.

Primary poisoning to birds. Tier 1. Long-term exposure

As mentioned in the EUBEES 2 guideline, the risk can be initially estimated from the PNEC covering long-term exposures.

Table 2.8.5.4.1.1.4: Tier 1 of primary poisoning to birds. Long-term risk characterization (chlorophacinone concentration 0.005%).

Organism	Maximum oral daily intake (mg a.s/kg food) PEC_{oral}	$PNEC_{birds}$ (mg a.s/kg food)	$PEC_{oral}/PNEC_{birds}$
Tree sparrow (22 g)	3 947	0.03	**131 600**
Chaffinch (21.4 g)	4 673	0.03	**155 767**
Wood pigeon (490 g)	565	0.03	**18 833**
Pheasant (953 g)	288	0.03	**9 600**

Conclusion: All values are higher than 1 suggesting a potential high risk. However, it should be considered that the use of a long-term PNEC is not realistic, as it assumes that the same non-target bird must ingest the bait every day.
Considering these results, it becomes necessary to perform a Tier 2 primary poisoning assessment in order to obtain more realistic conclusions.

Primary poisoning to mammals. Tier 2. Long-term exposure

According to the EUBEES 2, the risk characterization in Tier 2 is expressed in terms of dose. For this assessment, the $ENEL_{mammals}$ of about 0.00017-0.00006 mg a.s./kg bw is used.

Table 2.8.5.4.1.1.5: Tier 2. Long-term risk characterisation for different primary poisoning scenarios to mammals (chlorophacinone concentration 0.005%).

Exposure scenario (species, $ENEL_{mammal}$)	ETE (mg a.s/kg bw)		$ETE/ENEL_{mammals}$	
	First tier*	Second tier*	First tier*	Second tier*
Dog (0.00017-0.00006 mg a.s/kg bw)	3.0	2.2	**17 647-50 000**	**12 941-36 667**
Pig (0.00017-0.00006 mg a.s/kg bw)	0.4	0.3	**2 353-6 667**	**1 765-5 000**
Pig, young (0.00017-0.00006 mg a.s/kg bw)	1.2	0.9	**7 059-20 000**	**5 294-15 000**

*First tier (worst case) AV, PT = 1; Second tier (realistic worst case) AV = 0.9, PT = 0.8. Corrected for a maximum ingestion of 600 g bait..

All ETE values are higher than the NOAEL and the tentative risk quotients arevery high (1 765-36 667 at second tier) suggesting a potential high risk. However, it should be considered that the use of a long-term PNEC is not realistic, as it assumes that the same non-target mammal must ingest the bait every day. It is clear that at repeated doses the rodenticide poses a potential high risk to mammals, even at tier 2.

Primary poisoning to birds. Tier 2. Long-term exposure

Table 2.8.5.4.1.1.6: Tier 2. Long-term risk characterisation for different primary poisoning scenarios to birds (chlorophacinone concentration 0.005%).

Exposure scenario Species (bw), ($PNEC_{bird}$)	PEC (mg a.s/kg food) Realistic worst case	$PEC/PNEC_{birds}$ Realistic worst case

	First tier*	Second tier*	First tier*	Second tier*
Birds, (0.03 mg a.s/kg food)	50	36	**1 667**	**1 200**

*First tier (worst case) AV, PT and PD = 1; Second tier (realistic worst case) AV = 0.9, PT = 0.8 and PD =1.

Conclusion: In a long-term situation, all mammals and birds are potentially at risk of primary poisoning and mammals more than birds. To minimise the likelihood of target rodents developing resistance to anticoagulant rodenticides, long-term deployment of grain baits as a preventative control measure is not recommended. Product labels and approved guidance on good practice additionally instruct users to retrieve and securely dispose of all unconsumed baits at the end of control programmes. Both these factors limit the opportunity for exposure and reduce the primary poisoning risk to small non-target animals. Because of the toxic nature of rodenticides it is absolutely necessary to develop and validate risk management procedures in order to minimise the risk to non target animals.
If label instructions are followed, as should be the case for normal use, the primary poisoning risk should be negligible. The assessor should check what the exposure would be if the label conditions are followed. The reason is to assure that label instructions are fully adequate to mitigate intrinsic risk that these products potentially present (ESD, EUBEES 2).

2.8.5.4.1.2 Open areas

The primary poisoning risks to birds and mammals from ingestion of grain baits are assumed to be very low in open areas because delivery to the target animals is direct, the bait is not visible from above ground when the tunnel openings have been covered over and because the target rodents are unlikely to move pieces of grain baits from protection underground to places where they may become accessible to non-target birds and mammals.

It is not possible to quantify the amount of grain baits that may be exposed for ingestion by non-target birds and mammals. The levels of risk are considered to be very low, but in any event they are adequately covered by the assessments made above for various amounts of grain baits directly ingested following use in and around buildings.

2.8.5.4.1.3 Waste dumps

It is not possible to estimate the amount of grain baits that may be exposed for ingestion by non-target birds and mammals. Given that the attraction of waste dumps to the predominantly scavenging animals drawn there lies in the abundant availability of alternative food items, fragments of dyed grain baits formulated to appeal specifically to target rodents would seem unlikely to make significant contributions to the daily food intake of individual non-target birds and mammals. The levels of risk are considered to be adequately represented by the assessments made above for various amounts of grain baits directly ingested following use in and around buildings.

2.8.5.4.2 Secondary poisoning

2.8.5.4.2.1 In and around buildings

Secondary poisoning to mammals. Short-term exposure
Table 2.8.5.4.2.1.1: Tier 2 for secondary poisoning for non-target mammals containing chlorophacinone obtained from areas in and around buildings. Short-term exposure. Qualitative approach.

Bait consumption	**ETE** $_{predator}$ (mg a.s./kg predator bw)
based on residues in the rat after 5 days of ingestion after last meal	
20% normal situation Fox *Vulpes vulpes* (5,700 g; 520.2 g food (rat in this case)/d DFI)	0.02*
50% intermediate	0.04*
100% realistic worst case (not for foxes)	0.08*
20% Polecat *Mustela putorius* (689 g; 130.9 g/d DFI)	0.04*
50%	0.09*
100%	0.18*
20% Stoat *Mustela erminea* (205 g; 55.7 g/d DFI)	0.05*
50%	0.12*
100%	0.25*
20% Weasel *Mustela nivalis* (63 g; 24.7 g/d DFI)	0.07*
50%	0.18*
100%	0.36*

* Based on a $PEC_{oral\ predator}$ of 0.19, 0.46 and 0.93 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

The lowest acute endpoint is for dog LD_{50} « 2 mg a.s/kg bw. All values are below the threshold of the acute endpoint (although the uncertainty in the test for dogs still remains since the endpoint value is expressed as much lower than 2 mg a.s/kg bw). The level of the risk is not clarified with this approach, as an ETE below the LD_{50} does not indicate the absence of unacceptable risk if the required margin of safety is not established.

Secondary poisoning to birds. Short-term exposure

Table 2.8.5.4.2.1.2: Tier 2 for secondary poisoning for non-target birds containing chlorophacinone obtained from areas in and around buildings. Short-term exposure. Qualitative approach.

Bait consumption	**ETE** $_{birds}$ (mg a.s./kg predator bw)
based on residues in the rat after 5 days of ingestion after last meal	
20% Barn owl *Tyto alba* (294 g bw; 72.9 g food (rat in this case, Daily Food Intake)	0.05*
50%	0.11*
100%	0.23*
20% Kestrel *Falco tinnunculus* (209 g bw; 78.7 g DFI)	0.07*
50%	0.17*
100%	0.35*
20% Little owl *Athene noctua* (164 g bw;46.4 g DFI)	0.05*
50%	0.30*
100%	0.61*
20% Tawny owl *Strix aluco* (426 g bw; 97.1 g DFI)	0.04*
50%	0.10*
100%	0.21*

* Based on a $PEC_{oral\ predator}$ of 0.19, 0.46 and 0.93 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

The lowest acute endpoint is for *C. virginianus* LD_{50} = 257 mg a.s/kg bw. All values are below the acute endpoint. The qualitative approach for the acute situation gives no information neither for mammals nor for birds for the secondary poisoning since an ETE below the LD_{50} does not indicate the absence of unacceptable risk if the required margin of safety is not established.

Secondary poisoning long-term exposure

Secondary poisoning to mammals. Tier 1. Long-term exposure

Table 2.8.5.4.2.1.3: Tier 1 for secondary poisoning for non-target mammals. Long-term risk characterization.

Bait consumption	$ETE_{predator}$ (mg a.s/kg bw)	$PEC_{oral\ predator}$ (mg a.s./kg food)	$ENEL_{mammals}$ (mg a.s./kg bw)	$PNEC_{mammals}$ (mg a.s·kg $food^{-1}$)	$ETE/ENEL_{mammals}$	$PEC/PNEC_{mammals}$
based on residues in the rat after 5 days of ingestion after last meal						
20% normal situation Fox (5 700 g; 520.2 g food (rat in this case/d DFI)	0.1*	1.4	0.00017-0.00006	0.0011	588-1 667	1 273
50% intermediate	0.3*	3.4	0.00017-0.00006	0.0011	1 765-5 000	3 091
100% realistic worst case (not for foxes)	0.6*	7.0	0.00017-0.00006	0.0011	3 529-10 000	6 364
20% Polecat (689 g; 130.9 g/d DFI)	0.3*	1.4	0.00017-0.00006	0.0011	1 765-5 000	1 273
50%	0.7*	3.4	0.00017-0.00006	0.0011	4 118-11 667	3 091
100%	1.3*	7.0	0.00017-0.00006	0.0011	7 647-21 667	6 364
20% Stoat (205 g; 55.7 g/d DFI)	0.4*	1.4	0.00017-0.00006	0.0011	2 353-6 667	1 273
50%	1.0*	3.4	0.00017-0.00006	0.0011	5 882-16 667	3 091
100%	1.9*	7.0	0.00017-0.00006	0.0011	11 176-31 667	6 364
20% Weasel (63 g; 24.7 g/d DFI)	0.5*	1.4	0.00017-0.00006	0.0011	2 941-8 333	1 273
50%	1.4*	3.4	0.00017-0.00006	0.0011	8 235-23 333	3 091
100%	2.7*	7.0	0.00017-0.00006	0.0011	15 882-45 000	6 364
Based on residues in rodents after 14 days of ingestion after meal. Resistance situation						
20% Fox	0.2**	1.7	0.00017-0.00006	0.0011	1 176-3 333	1 545
50%	0.4**	4.2	0.00017-0.00006	0.0011	2 353-6 667	3 818

100%	0.8**	8.3	0.00017-0.00006	0.0011	4 706-13 333	7 545
20% Polecat	0.3**	1.7	0.00017-0.00006	0.0011	1 765-5 000	1 545
50%	0.8**	4.2	0.00017-0.00006	0.0011	4 706-13 333	3 818
100%	1.6**	8.3	0.00017-0.00006	0.0011	9 412-26 667	7 545
20% Stoat	0.5**	1.7	0.00017-0.00006	0.0011	2 941-8 333	1 545
50%	1.1**	4.2	0.00017-0.00006	0.0011	6 470-18 333	3 818
100%	2.2**	8.3	0.00017-0.00006	0.0011	12 941-36 667	7 545
20% Weasel	0.7**	1.7	0.00017-0.00006	0.0011	4 118-11 667	1 545
50%	1.6**	4.2	0.00017-0.00006	0.0011	9 412-26 667	3 818
100%	3.2**	8.3	0.00017-0.00006	0.0011	18 824-53 333	7 545

* Based on a $PEC_{oral\ predator}$ of 1.4, 3.5 and 7.0 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

** Based on a $PEC_{oral\ predator}$ of 1.7, 4.2 and 8.3 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

For long-term exposures all values are much higher than 1 suggesting a potential the risk of secondary poisoning to mammals increases drastically in comparison to the short-term risk.

Secondary poisoning for birds. Tier 1. Long-term exposure

Table 2.8.5.4.2.1.4: Tier 1 for secondary poisoning for non-target birds. Long-term risk characterization.

Bait consumption	**$PEC_{oral\ bird}$** (mg a.s./kg food)	**$PNEC_{bird}$** (mg a.s./kg food)	**$PEC/\ PNEC_{birds}$**
based on residues in the rat after 5 days of ingestion after last meal			
20%	1.4	0.03	**46.7**
50%	3.4	0.03	**113.3**
100%	7.0	0.03	**233.3**
Based on residues in rodents after 14 days of ingestion after meal. Resistance situation			
20%	1.7	0.03	**56.7**
50%	4.2	0.03	**140.0**
100%	8.3	0.03	**276.7**

* Based on a PEC_{oral} of 1.4, 3.4 and 7.0 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

** Based on a PEC_{oral} of 1.7, 4.2 and 8.3 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

All birds are at risk of long-term secondary poisoning regardless their body weight or daily food intake. But even in this situation the risk posed is lower to birds than to mammals as it was expected.

Conclusion: As a conclusion it can be said that small mammals and birds are the most sensitive organisms; being the mammals more prone to primary and secondary poisoning than birds.

These risks estimations have been confirmed by two short-term dietary semi-field studies (CAR chlorophacinone Doc. III-A 7.5.6-01 *Pica pica* and 02 ferrets, *Mustela putorius furo*) where there is a significant risk of secondary poisoning for mammals (55% mortalities) and a much lower risk to birds (no mortalities reported) (see also CAR chlorophacinone Doc. II-A).

Tier 2 of secondary poisoning with measured residues of chlorophacinone in target rodents
In the table below the various concentrations of chlorophacinone in target rodents on day 5 and day 7 have been lowered *pro rata* to reflect real, measured residues instead of the estimated values based on kinetics.

Table 2.8.5.4.2.1.5: Residues of chlorophacinone in target rodents from the ingestion of baits at different times during a control campaign, based on the maximum residue level measured in rats (measured in homogenised whole-body tissues of rat carcasses).

Time	**Residues of chlorophacinone in target rodent (mg a.s./kg rat bw) $EC_{refined}$**		
	20% bait consumption	**50% bait consumption**	**100% bait consumption**
Day 5 after last meal[1]	**0.19**	**0.46**	**0.93**
Day 7 (mean time to death)[2]	0.10	0.24	0.47
[1] Based on 0.9272 mg/kg bw measured after 100% bait consumption for 5 days (see Doc. III-A 7.5.6-01); [2] Based on excretion of 30% per day and a reduction of approximately 50% between days 5 and 7.			

Due to the incidents occurred in Spain in February 2007, a group of experts from the INIA sampled the area and collected carcasses from common voles (*Microtus arvalis*) in order to analyse residues of chlorophacinone in their bodies. Chlorophacinone was extracted and the analysis was carried out with an HPLC-mass spectrometry. The Limit Of Detection (LOD) was ≥ 20 ng/g wet weight and the Limit Of Quantification, LOQ, ≥ 30 ng/g wet weight. The concentrations found varied from the LOD up to 0.5 µg/g bw. Considering a mean weight of 20-30 g and an uniform distribution of the substance in the whole organism, the maximum quantity of rodenticide per animal would be between 10 and 15 µg cpn. These results are in line with those described in the bibliography (Primus Th.M. et al. (2001)[28]).

This incident also offered indications, not confirmed, of secondary poisoning of mammals with levels clearly much lower than those used in the EUBEES 2 guideline and similar to the ones provided by the notifier.

[28] Primus Th.M, Eisemann J.D., Matschke G.H. Ramey C., Johnston J.J (2001). Chlorophacinone residues in Rangeland rodents: An assessment of the potencial risk of secondary toxicity to scavengers. En: *Pesticides and Wildlife*. Editos: Johnstan J.J. ACS Symposium Series 771. American Chemical Society. Washintong DC. Pp. 164-180.

Table 2.8.5.4.2.1.6: Residues of chlorophacinone in target rodents from the ingestion of grain baits at different times during a control campaign, based on the maximum residue level measured in rats. Long-term exposure.

Time	Residues of chlorophacinone in target rodent (mg a.s./kg rat bw) $EC_{refined}$		
	20% bait consumption	**50% bait consumption**	**100% bait consumption**
Day 5 after last meal[1]	**0.10**	**0.23**	**0.46**
Day 7 (mean time to death)[2]	0.05	0.12	0.23
[1] Based on 0.9272 mg/kg bw measured after 100% bait consumption for 5 days (see Doc. III-A 7.5.6-01); [2] Based on excretion of 30% per day and a reduction of approximately 50% between days 5 and 7.			

Secondary poisoning for mammals. Tier 2. Long-term exposure

Exposure levels (ETE) have been estimated from the semifield studies. Even for this refined assessment, all exposure levels are higher that the rat NO(A)EL of 0.005 mg a.s/kg bw. In addition, the ETEs have been compared with the tentative Estimated No Effect Level which is presented as a range. The risk quotients (ETE/ENEL) are summarised in the table below.

Table 2.8.5.4.2.1.7: Tier 2 for secondary poisoning for non-target mammals containing chlorophacinone obtained from areas in and around buildings. Long-term risk characterization

Bait consumption	$ETE_{predator}$ (mg a.s./kg predator bw)	$ENEL_{mammals}$ (mg a.s./kg predator bw)	ETE/ENEL mammals
Based on residues in the rat after 5 days of ingestion after last meal			
20% normal situation Fox *Vulpes vulpes* (5,700 g; 520.2 g food (rat in this case)/d DFI)	0.01*	0.00017-0.00006	**59-167**
50% intermediate	0.02*	0.00017-0.00006	**118-333**
100% realistic worst case (not for foxes)	0.04*	0.00017-0.00006	**235-667**
20% Polecat *Mustela putorius* (689 g; 130.9 g/d DFI)	0.02*	0.00017-0.00006	**118-333**
50%	0.04*	0.00017-0.00006	**235-667**
100%	0.08*	0.00017-0.00006	**470-1 333**
20% Stoat *Mustela erminea* (205 g; 55.7 g/d DFI)	0.02*	0.00017-0.00006	**118-333**
50%	0.06*	0.00017-0.00006	**353-1 000**
100%	0.12*	0.00017-0.00006	**706-2 000**
20% Weasel *Mustela nivalis* (63 g; 24.7 g/d DFI)	0.04*	0.00017-0.00006	**235-667**
50%	0.09*	0.00017-0.00006	**529-1 500**
100%	0.18*	0.00017-0.00006	**1 059-3 000**

* Based on a $PEC_{oral\ predator}$ of 0.10, 0.23 and 0.46 mg a.s/kg rat bw, for a bait consumption of 20, 50 and 100% respectively

The rapporteur suggests the additional estimation of the short-term risk, to estimate the risk associated to a single ingestion of rat carcasses, compared to a short-term PNEC derived from single dose toxicity data.

The long-term secondary poisoning to mammals still remains. Only the application of proper risk reduction measures will fit for the purpose of abating this potential risk.

Secondary poisoning to birds. Tier 2. Long-term exposure

No reliable long-term toxicity studies on birds have been submitted, and therefore, the only possible comparisons are with the $PNEC_{birds}$ estimated from short-term studies, which is supported by additional information.

Table 2.8.5.4.2.1.8: Tier 2 for secondary poisoning for non-target birds containing chlorophacinone obtained from areas in and around buildings. Long-term risk characterization.

Bait consumption	$PEC_{oral\ bird}$ (mg a.s./kg food)	$PNEC_{bird}$ (mg a.s./kg food)	$PEC/PNEC_{birds}$
Based on residues in the rat after 5 days of ingestion after last meal. No resistance situation			
20%	0.10	0.03	**3.3**
50%	0.23	0.03	**7.7**
100%	0.46	0.03	**15.3**
Based on residues in the rat after day 14 just after last meal. Resistance situation			
20%	0.05	0.03	**1.7**
50%	0.12	0.03	**4.0**
100%	0.23	0.03	**7.7**

It is stated in the CAR of substance active that the rapporteur suggests the additional estimation of the short-term risk, to estimate the risk associated to a single ingestion of rat carcasses, compared to a short-term PNEC derived from single dose toxicity data. The refinement has lowered the ratios several times but there is still a long-term risk of secondary poisoning to birds.
In a long-term situation, all mammals and birds are potentially at risk of primary poisoning and mammals more than birds. To minimise the likelihood of target rodents developing resistance to anticoagulant rodenticides, long-term deployment of grain baits as a preventative control measure is not recommended. Product labels and approved guidance on good practice additionally instruct users to retrieve and securely dispose of all unconsumed baits at the end of control programmes. Both these factors limit the opportunity for exposure and reduce the primary poisoning risk to small non-target animals. Because of the toxic nature of rodenticides it is absolutely necessary to develop and validate risk management procedures in order to minimise the risk to non target animals.

Conclusion: it can be said that small mammals and birds are the most sensitive organisms; being mammals more prone to primary and secondary poisoning than birds. These risks estimations have been confirmed by two short-term dietary semi-field studies (*Pica pica* and ferrets, *Mustela putorius furo*) where there is a significant risk of secondary poisoning for mammals (55% mortalities) and a much lower risk to birds (no mortalities reported).

2.8.5.4.2.2 Open areas

The secondary poisoning risks to birds and mammals following the use of grain baits containing chlorophacinone in open areas are adequately quantified for uses in and around buildings as above.

2.8.5.4.2.3 Waste dumps

The secondary poisoning risks to birds and mammals following the use of baits containing chlorophacinone in waste dumps are adequately quantified for uses in and around buildings as above.

Conclusion of the risk assessment for the environment

No studies were conducted with the product CAID GRAIN'TECH for the environment part; therefore the environmental risk assessment has been carried out with data from the CAR of chlorophacinone. The environmental risk is considered as limited for the indoor use by non-professionals and for the use in and around building by professionals, in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning.
Nevertheless, the Authority in charge of the efficacy and risk assessment is not able to assess the applicability of the specific use instructions and restrictions for:

- the outdoor applications by non-professionals,
- the use in open area by professionals,
- the use in waste dump by professionals.

Risk mitigation measures linked to risk assessment

For professional users (in and around buildings)

- Dispose of the bait boxes or bait stations, non-consumed baits and dead rodents in accordance with local requirements.
- Never wash the bait boxes or bait stations with water.
- Place the bait boxes and bait stations in sites sheltered from rain and flooding.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
- Collect non-consumed baits and dead rodents during and after treatment.
- In order to prevent primary and secondary poisoning for children, for domestic and wild animals, bait points must be securely deposited, and placed in non accessible areas.
- Use bait stations or bait boxes. In order to prevent primary and secondary poisoning for children, for domestic and wild animals, bait points must be securely deposited, and placed in non accessible areas.
- Remove all the bait boxes or bait stations after the treatment.

For non professional users (indoor buildings)

- Dispose of the bait boxes, non-consumed baits and dead rodents in accordance with local requirements.
- Never wash the bait boxes with water.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
- Collect non-consumed baits and dead rodents during and after treatment.
- In order to prevent primary and secondary poisoning for children, for domestic and wild animals, bait points must be securely deposited, and placed in non accessible areas.
- Use only in tamper-resistant secured bait boxes. Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides. These bait boxes must not be used for other products than rodenticides.
- Remove all the bait boxes after the treatment.

Required information linked to environment assessment
The identification of the major metabolite M1 observed in the study of photolysis in water that had not been asked to stage the inclusion of the active substance as well as the characterization its dangers are required and have to be provided within three years post authorization.

2.9 Measures to protect man, animals and the environment as proposed by the applicant

See Summary of Product Characteristics (SPC).

3 PROPOSAL FROM AUTHORITY IN CHARGE OF THE RISK ASSESSMENT (ANSES) FOR THE DECISION TO BE ADOPTED BY THE COMPETENT AUTHORITY IN CHARGE OF THE DECISION (FRENCH MINISTRY OF ECOLOGY)

This section is a proposal from the authority in charge of the risk assessment (ANSES) for the decision to be adopted by the competent authority in charge of the decision (French Ministry of Ecology).
In case of inconsistency between the risk assessment and the decision, only the original and signed decision has a legal value. The decision specifies the terms and conditions to the making available on the market and use of the biocidal product.

Conclusions of efficacy and risk assessment

Risk assessment for Physico-chemical properties

CAID GRAIN'TECH is a grain ready-to-use rodenticide. It is not highly flammable, not auto-flammable at ambient temperature, not explosive and does not have oxidizing properties.
Results of the accelerated storage study should be confirmed by a new study in post registration. The product CAID GRAIN'TECH is stable 3.5 years at ambient temperature and compatible with PE sachet, PP sachet and paper laminate sachet of 20 g which covers all the claimed packagings.

Summary of efficacy assessment
The product CAID GRAIN'TECH has shown a sufficient efficacy and can be used in accordance with the risk assessment for the control of mice (*Mus musculus*) and rats (*Rattus norvegicus* and *Rattus rattus*) inside and around domestic, industrial and commercial buildings including in farm buildings. Nevertheless, a monitoring of the resistance phenomenon of rodent populations toward the active substance chlorophacinone and resistant strategies management must be put in place. The collected information must be sent every 2 years to Anses within the framework of a post-authorization monitoring.

Summary of risks characterisation of the product for human health

No unacceptable risk was observed from the intended uses (professional and non professional) whatever the type of formulation considered (in bulk or in sachet) for the treatment of rats and mice. Gloves are anyway recommended to help prevent rodent-borne disease.

Based on a reverse scenario, more than 6.6 mg of product per day should be ingested by an infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if CAID GRAIN'TECH contains a bittering agent which reduces the likelihood of ingestion, the baits should be placed in areas which do not allow access to children and in secured bait boxes. Product label ("do not open the sachet") and good practice advise users to prevent access to bait by children and infants.

Summary of risks characterisation of the product for consumer

The intended use descriptions of the chlorphacinone-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff.

Summary of risks characterisation of the product for the environment

No studies were conducted with the product CAID GRAIN'TECH for the environment part; therefore the environmental risk assessment has been carried out with data from the CAR of chlorophacinone. The environmental risk is considered as limited for the indoor use by non-professionals and for the use in and around building by professionals, in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning.

Nevertheless, the Authority in charge of the efficacy and risk assessment is not able to assess the applicability of the specific use instructions and restrictions for:
- the outdoor applications by non-professionals ;
- the use in open area by professionals ;
- the use in waste dump by professionals.

Risk mitigation measures and conditions of use

Risk mitigation measures linked to assessment of physico-chemical properties

- Store away from light

Risk mitigation measures linked to efficacy assessment

For professional users:

- Adapt the number of bait station to the infestation level.
- Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.
- The label has to respect the recommended conditions of use and the biocidal products labelling guide[29].
- The amount of bait per bait station and distances between bait stations must be respected. Products have always to be used in accordance with the label.
- To avoid resistance:
    - Adapt the quantity of bait per bait station to the validated effective dose.

[29] Guide à l'intention des responsables de la mise sur le marché des produits biocides. Lignes directrices sur l'étiquetage des produits biocides mis sur le marché. Version du 28 août 2007.

- The product label has to contain information on resistance management for rodenticides
- The treatment has to be alternated with other kinds of active substances having different modes of action.
- The level of efficacy have to be monitored (periodic check), and the case of reduced efficacy has to be investigated for possible evidence of resistance.
- Resistant management strategies have to be developed.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures.
- The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
- do not use the product in areas where resistance is suspected or established.

For non professional users:

- Adapt the number of bait station to the infestation level.
- Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed.
- The label has to respect the recommended conditions of use and the biocidal products labelling guide[30].
- The amount of bait per bait station and distances between bait stations must be respected. Products have always to be used in accordance with the label.
- To avoid resistance:
    - Adapt the quantity of bait per bait station to the validated effective dose.
    - The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

Risk mitigation measures linked to risk assessment for human health

For professional users

- Gloves have to be worn to help prevention against rodent-borne disease
- Bait stations must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Do not open the sachet
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Tamper-resistant bait stations should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Other covered or not covered bait points could be used. These stations must be placed only in areas not accessible to the general public and non-target animals.
- Collect uneaten bait, debris dragged away from the box or bait station and dead rodents, during and after treatment.
- Remove all bait stations (boxes or other bait stations) after the end of treatment.

For non professional users

- Do not open the sachet

[30] Guide à l'intention des responsables de la mise sur le marché des produits biocides. Lignes directrices sur l'étiquetage des produits biocides mis sur le marché. Version du 28 août 2007.

- Use only in tamper-resistant bait stations. Tamper-resistant bait stations should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Bait stations must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
- Collect uneaten bait, debris dragged away from the box or bait station and dead rodents, during and after treatment.
- Remove all bait boxes after the end of treatment.

Risk mitigation measures linked to risk assessment for consumer

- The intended use descriptions of the chlorphacinone-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff.

Risk mitigation measures linked to risk assessment for environment

For professional users (in and around buildings)

- Dispose of the bait boxes or bait stations, non-consumed baits and dead rodents in accordance with local requirements.
- Never wash the bait boxes or bait stations with water.
- Place the bait boxes and bait stations in sites sheltered from rain and flooding.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
- Collect non-consumed baits and dead rodents during and after treatment.
- In order to prevent primary and secondary poisoning for children, for domestic and wild animals, bait points must be securely deposited, and placed in non accessible areas.
- Use bait stations or bait boxes. In order to prevent primary and secondary poisoning for children, for domestic and wild animals, bait points must be securely deposited, and placed in non accessible areas.
- Remove all the bait boxes or bait stations after the treatment.

For non-professional users (indoor buildings)

- Dispose of the bait boxes, non-consumed baits and dead rodents in accordance with local requirements.
- Never wash the bait boxes with water.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
- Collect non-consumed baits and dead rodents during and after treatment.
- In order to prevent primary and secondary poisoning for children, for domestic and wild animals, bait points must be securely deposited, and placed in non accessible areas.
- Use only in tamper-resistant secured bait boxes. Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides. These bait boxes must not be used for other products than rodenticides.

Disposal considerations

- Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.

- Remove all bait points after the end of treatment.
- Dispose of the tamper-resistant bait boxes and covered bait stations, uneaten baits and dead rodents in accordance with local requirements.
- Never wash the tamper-resistant bait boxes and covered bait stations with water.
- Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

Information required post-authorisation

Required information linked to assessment of physico-chemical properties
An accelerated storage stability study (14 days at 54℃ or at a lower temperature) with CIPAC MT46 is required in post registration.

Further validation data of the analytical method for the determination of chlorophacinone in the product CAID GRAIN'TECH are required in post registration (specificity and repeatability).

Required information linked to efficacy assessment
The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

Required information linked to environment assessment
The identification of the major metabolite M1 observed in the study of photolysis in water that had not been asked to stage the inclusion of the active substance as well as the characterization its dangers are required and have to be provided within three years post authorization.

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Annex 0: Practical use of Biocides ex: TP14

Name of the product and type of formulation (grains, powder, paste, block…)	Target organism (rat, mice…)*	User category (professional/non professional)*	Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps,…)*	Dosage claimed expressed in g/bait point, for high and low infestation (if appropriate)	Time delay of the action of the product	Frequency and method of controls	Size(s) of the bait (g/bloc, g/grain, g/sachet, g/paste …)	Distance between 2 bait points, for high and low infestation (if appropriate)	Methods of application of the bait (ex: pre-filled secured bait box)	Package details : Individual packaging (yes/no)**	Primary packaging : type : bulk, individual wrapping…/ nature: bucket, bottle, sachet…/ material: paper, polyethylene…/ sizes	Secondary packaging
CAID GRAIN TECH **Formulation: LR0191_02**	Rats	Professional	In and around buildings	Up to 200 g *This level is adapted according to the size of the sachet*	5 to 7 days after the first consumption	High infestation 3 days after first application then ideally every week or 15 days Low infestation 1 week after first application then ideally every week or 15 days If consumption is complete, repeat the treatment without exceeding the dose of 200g	Loose, or in sachets 20g to 100g	4 to 5 meters High infestation 8 to 10 meters low infestation	Grain baits are manually placed in the rodent infested area. Methods of deployment for professional users are bait stations (tamper proof boxes), bait points (a makeshift arrangement which uses materials and/or the local environment to	Yes	Packaging: sachet Material: PE or PP (Opaque or transparent)	Opaque Metal box 500g to 1 kg Opaque Plastic lockable pouch PE or PP 500g to 20 kg Opaque Plastic bucket (PP) with lid 500g to 25 kg Opaque Cardboard carton 500g to 25 kg Opaque plastic container (PE or PP) 500g to 4 kg Opaque Paper laminate bag 500g to 25 kg
										No	Opaque Plastic lockable pouch PE or PP 500g to 20 kg Opaque Plastic bucket (PP) with lid 500g to 25 kg Opaque Cardboard carton with integral PE bag 500g to 25 kg Opaque plastic container	

									restrict access to the bait), loose but inaccessible (an arrangement which uses the local environment only to restrict access to the bait), burrows		(PE or PP) 500g to 4 kg Opaque Paper laminate bag 500g to 25 kg	
	Mice	Professional	In and around building	Up to 100 g *This level is adapted according to the size of the sachet*	5 to 7 days after the first consumption consumption	High infestation 3 days after first application then ideally every week or 15 days Low infestation 1 week after first application then ideally every week or 15 days If consumption is complete, repeat the treatment without exceeding the dose of 100g	Loose, or in sachets 20g to 50g	1 to 1.5 meters in high infestation 2 to 3 meters in low infestation	Grain baits are manually placed in the rodent infested area. Methods of deployment for professional users are bait stations (tamper proof boxes), bait points (a makeshift arrangement which uses materials and/or the local environment to restrict access to the bait), loose but inaccessible (an arrangement which uses the local environment only to restrict access to the bait), burrows	YES	Packaging: sachet Material: PE or PP (Opaque or transparent)	Opaque Metal box 500g to 1 kg Opaque Plastic lockable pouch PE or PP 500g to 20 kg Opaque Plastic bucket (PP) with lid 500g to 25 kg Opaque Cardboard carton 500g to 25 kg Opaque plastic container (PE or PP) 500g to 4 kg Opaque Paper laminate bag 500g to 25 kg
										NO	Opaque Plastic lockable pouch PE or PP 500g to 20 kg Opaque Plastic bucket (PP) with lid 500g to 25 kg Opaque Cardboard carton with an integral PE bag 500g to 25 kg Opaque plastic container (PE or PP) 500g to 4 kg Opaque Paper laminate bag 500g to 25 kg	
	Rats	Professional	Open areas	Up to 200 g *This level is adapted according to the size of the sachet*	5 to 7 days after the first consumption	High infestation 3 days after first application then ideally every month Low infestation	Loose, or in sachets 20g to 100g	NA In the burrows 10-15 m low	Grain baits are manually placed in the rodent infested area.	YES	Packaging: sachet Material: PE or PP (Opaque or transparent)	Opaque Metal box 500g to 1 kg Opaque Plastic lockable pouch PE or PP 500g to 20 kg Opaque Plastic bucket (PP)

						1 week after first application then ideally every month If consumption is complete, repeat the treatment without exceeding the dose of 200g		infestation 3-5 m high infestation (depends also on the configuration of the site)	Methods of deployment for professional users are bait stations (tamper proof boxes) or in burrow			with lid 500g to 25 kg Opaque Cardboard carton 500g to 25 kg Opaque plastic container (PE or PP)) 500g to 4 kg Opaque Paper laminate bag 500g to 25 kg
										NO	Opaque Plastic lockable pouch PE or PP 500g to 20 kg Opaque Plastic bucket (PP) with lid 500g to 25 kg Opaque Cardboard carton with integral PE bag 500g to 25 kg Opaque plastic container (PE or PP) 500g to 4 kg Opaque Paper laminate bag 500g to 25 kg	
	Mice	Professional	Open areas	Up to 100 g *This level is adapted according to the size of the sachet*	5 to 7 days after the first consumption	High infestation 3 days after first application then ideally every month Low infestation 1 week after first application then ideally every month If consumption is complete, repeat the treatment without exceeding the dose of 100g	Loose, or in sachets 20g to 50g	NA In the burrows 10-15 m low infestation 3-5 m high infestation (depends also on the configuration of the site)	Grain baits are manually placed in the rodent infested area. Methods of deployment for professional users are bait stations (tamper proof boxes) or in burrow	YES	Packaging: sachet Material: PE or PP (Opaque or transparent)	Opaque Metal box 500g to 1 kg Opaque Plastic lockable pouch PE or PP 500g to 20 kg Opaque Plastic bucket (PP) with lid 500g to 25 kg Opaque Cardboard carton 500g to 25 kg Opaque plastic container (PE or PP) 500g to 4 kg Opaque Paper laminate bag 500g to 25 kg
										NO	Opaque Plastic lockable pouch PE or PP 500g to 20 kg Opaque Plastic bucket (PP) with lid 500g to 25 kg	

											Opaque Cardboard carton with integral PE bag 500g to 25 kg	
											Opaque plastic container (PE or PP) 500g to 4 kg	
											Opaque Paper laminate bag 500g to 25 kg	
												Opaque Plastic lockable pouch PE or PP 500g to 20 kg
												Opaque Plastic bucket (PP) with lid 500g to 25 kg
												Opaque Cardboard carton 500g to 25 kg
												Opaque plastic container (PE or PP) 500g to 4 kg
												Opaque Paper laminate bag 500g to 25 kg
	Rats	Professional	Waste dump	Up to 200g *This level is adapted according to the size of the sachet*	5 to 7 days after the first consumption	Application every 2 to 3 months If consumption is complete, repeat the treatment without exceeding the dose of 200g	Loose, or in sachets 20g to 100g	NA In the burrows 10-15 m low infestation 3-5 m high infestation (depends also on the configuration of the site)	Grain baits are manually placed in the rodent infested area. Methods of deployment for professional users are bait stations (tamper proof boxes), bait points (a makeshift arrangement which uses materials and/or the local environment to restrict access to the bait), burrows	YES	Packaging: sachet Material: PE or PP (Opaque or transparent)	Opaque Metal box up to 1 kg
												Opaque Plastic lockable pouch PE or PP 500g to 20 kg
												Opaque Plastic bucket (PP) with lid 500g to 25 kg
												Opaque Cardboard carton 500g to 25 kg
												Opaque plastic container (PE or PP) 500g to 4 kg
												Opaque Paper laminate bag 500g to 25 kg
										NO	Opaque Plastic lockable pouch PE or PP 500g to 20 kg	
											Opaque Plastic bucket (PP) with lid 500g to 25 kg	
											Opaque Cardboard carton with integral PE bag 500g to 25 kg	
											Opaque plastic container (PE or PP) 500g to 4 kg	
											Opaque Paper laminate bag	

											500g to 25 kg	
	Mice	Amateur	In and around building	Up to 100g *This level is adapted according to the size of the sachet*	5 to 7 days after the first consumption	High infestation 3 days after first application then ideally every week or 15 days Low infestation 1 week after first application then ideally every week or 15 days If consumption is complete, repeat the treatment without exceeding the dose of 100g	Loose, or in sachets 20g to 50g	1 to 1.5 meters in high infestation 2 to 3 meters in low infestation	Grain baits are manually placed in the rodent infested area. Methods of deployment for amateur users are bait stations (tamper proof boxes), bait points (a makeshift arrangement which uses materials and/or the local environment to restrict access to the bait), loose but inaccessible (an arrangement which uses the local environment only to restrict access to the bait).	YES	Packaging: sachet Material: PE or PP (Opaque or transparent)	Opaque Metal box 40g to 1 kg Opaque Plastic lockable pouch PE or PP 40g to 4 kg Opaque plastic bucket (PP) with lid 40g to 4 kg Opaque Cardboard carton with 40g to 4 kg Opaque plastic container (PE or PP) 40g to 4 kg
										NO	Opaque Plastic lockable pouch PE or PP 40g to 4 kg Opaque Plastic bucket (PP) with lid 40g to 4 kg Opaque Cardboard carton with integral PE bag 40g to 4 kg Opaque plastic container (PE or PP) 40g to 4 kg	
	Rats	Amateur	In and around buildings	Up to 200 g *This level is adapted according to the size of the sachet*	5 to 7 days after the first consumption	High infestation 3 days after first application then ideally every week or 15 days Low infestation 1 week after first application then ideally every week or 15 days If consumption is complete, repeat the treatment without exceeding the dose of 200g	Loose, or in sachets 20g to 100g	4 to 5 meters High infestation 8 to 10 meters low infestation	Grain baits are manually placed in the rodent infested area. Methods of deployment for amateur users are bait stations (tamper proof boxes), bait points (a makeshift arrangement which uses materials and/or the local environment to restrict access to the bait), loose but inaccessible (an arrangement	YES	Packaging: sachet Material: PE or PP (Opaque or transparent)	Opaque Metal box 40g to 1 kg Opaque Plastic lockable pouch PE or PP 40g to 4 kg Opaque Plastic bucket (PP) with lid 40g to 4 kg Opaque Cardboard carton 40g to 4 kg Opaque plastic container (PE or PP) 40g to 4 kg
										NO	Opaque Plastic lockable pouch PE or PP 40g to 4 kg Opaque Plastic bucket (PP) with lid 40g to 4 kg Opaque Cardboard carton with integral PE bag 40g to 4 kg Opaque plastic container (PE or PP) 40g to 4 kg	

									which uses the local environment only to restrict access to the bait).			

Annex 1: Practical uses validated taking into account the risk assessment

This chart reflects the results of the risk assessment. In case of differences between the uses suggested by Anses to be authorised and the uses contained in the decision taken by the French ministry, only the original and signed decision has a legal value.

Target organisms	Area of use	Dosage claimed	Time delay of the action of the product	Frequency and method of controls	Distance between 2 bait points, for high and low infestation	Methods of application of the bait	
Professional users							
Rats	In and around building	200 g / bait point	3 to 14 days	Inspect and resupply the bait points, 3 days after application then once a week as long as the bait is consumed.	4-5 meters 8-10 meters	Manual application in bait stations or bait points.	**Polyprolylene (PP) or polyethylene (PE), opaque or transparent sachets (20-100 g for rats and 20-50 g for mice) are packed in:** - Opaque metal box (500 g-1kg) ; - PE or PP opaque lockable pouch (500 g-20 kg) ; - PP opaque bucket (500 g-25 kg) ; - Opaque cardboard carton (500 g-25 kg) ; - PE or PP opaque container (500 g-4 kg) ; - Opaque paper laminate bag (500g-25 kg). **Loose baits are packed in:** - PE or PP opaque lockable pouch (500 g-20 kg) ; - PP opaque bucket (500 g-25 kg) ;PE bag in opaque cardboard carton (500 g-25kg) ; - PE or PP opaque container (500 g-4kg) ; - Opaque paper laminate bag (500 g-25kg).
Mice		100 g / bait point	3 to 14 days 3 to 14 days		1-1.5 meters 2-3 meters		

Non professional users							
Rats	In and around building	200 g / bait point	3 to 14 days	Inspect and resupply the bait points, 3 days after application then once a week as long as the bait is consumed.	4-5 meters 8-10 meters	Manual application in bait stations	**PP or PE, opaque or transparent sachets (20-100g for rats and 20-50g for mice) are packed in:** - Opaque metal box (40 g-1kg) ; - PE or PP opaque lockable pouch (40 g-4 kg) ; - PP opaque bucket (40 g-4 kg) ; - Opaque cardboard carton (40 g-4 kg) ; - PE or PP opaque container (40 g-4kg). **Loose baits are packed in:** - PE or PP opaque lockable pouch (40 g-4 kg) ; - PP opaque bucket (40 g-4kg) ;PE bag in opaque cardboard carton (40 g-4 kg) ; - PE or PP opaque container (40 g-4 kg).
Mice		100 g / bait point	3 to 14 days		1-1.5 meters 2-3 meters		

Annex 2: List of studies reviewed

List of new data[31] submitted in support of the evaluation of the active substance

No new data[32] have been submitted in support of the evaluation of the active substance

List of new data 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
IIIB3.1.1-01 IIIB3.1.2-01 IIIB3.1.3-01		Caruel, H.	2007 a	Chlorophacinone red wheat 50 mg/kg CLOBL0,0050_05F_LR0191_00 Appearance, Colour, Odour	LiphaTech	☐	☒	☒	☐
IIIB3.1.1-01 IIIB3.1.2-01 IIIB3.1.3-01		Caruel, H.	2012	Amendment n°1 Chlorophacinone red wheat 50 mg/kg, Appearance, Colour, Odour CLOBL0,0050_05F_LR0191_00 CLO0701E	LiphaTech	☐	☒	☒	☐
		Caruel, H.	2011	Chlorophacinone Red Pellets 50 mg/kg Physical characterisation Pellets size	LiphaTech	☐	☒	☒	☐

31 Data which have not been already submitted for the purpose of the Annex I inclusion.
32 Data which have not been already submitted for the purpose of the Annex I inclusion.

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB3.2-01		Lindemann, M.	2004 a	Expert Statement on the explosive properties of chlorophacinone wheat (Caid appats).	LiphaTech	☐	☒	☒	☐
IIIB3.3-01		Lindemann, M.	2004 b	Expert Statement on the oxidizing properties of chlorophacinone wheat (Caid appats).	LiphaTech	☐	☒	☒	☐
IIIB 3.4-01		Lindemann, M.	2004 c	Determination of the relative self-ignition temperature of chlorophacinone wheat.	LiphaTech	☐	☒	☒	☐
IIIB 3.4-02		Lindemann, M.	2004 d	Determination of the flammability of chlorophacinone wheat.	LiphaTech	☐	☒	☒	☐
IIIB3.6-02 IIIB3.8-04 IIIB3.11		Ferron, N.	2012	Physico chemical tests on Chlorophacinone wheat 50 mg/kg	LiphaTech	☐	☒	☒	☐
IIIB3.7-01		Caruel, H	2007 b	Chlorophacinone red wheat 50 mg/kg accelerated storage stability (54℃, 14 days).	LiphaTech	☐	☒	☒	☐
IIIB3.7-01		Caruel, H	2012	Amendment n°1 CLO0702E Chlorophacinone red wheat 50 mg/kg accelerated storage stability (54℃, 14 days).	LiphaTech	☐	☒	☒	☐
IIIB3.7-04v2		Caruel, H.	2012	Chlorophacinone red wheat 50 mg/kg long term storage stability (25℃).	LiphaTech	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB3.7-05		Deslux, R.	2012	Chlorophacinone bait compatibility packaging study (54℃, 14days)	LiphaTech	☐	☒	☒	☐
IIIB4.1		Caruel, H.	2007	Chlorophacinone red wheat 75 and 50 mg/kg analytical methods validation	LiphaTech	☐	☒	☒	☐
IIIB4.1		Caruel, H.	2012	Amendment n°1 CLO0702D Chlorophacinone red wheat 75 and 50 mg/kg analytical methods validation	LiphaTech	☐	☒	☒	☐
IIIB 5.10.01		Berny, P.	2010	Study on the efficacy and palatability of a block at 50 mg/kg of chlorophacinone in the rat, *Rattus rattus*, wild strain, sensitive to warfarin. Laboratoire de Toxicologie, ENVL, laboratory report no. RE/1002/CPN/Block/Rr/S. March 2010 (unpublished).	LiphaTech S.A.S.	☐	☒	☒	☐
IIIB 5.10.1		Lorgue, G.	1999	Study on the efficacy and attractivity of a wheat bait based on chlorophacinone in the Norway rat, wild strain, *Rattus Norvegicus*. Laboratoire de Toxicologie, ENVL, laboratory report no. P.9903, 20 December 1999 (unpublished).	LiphaTech S.A.S.	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB 5.10.2		Berny, P.	2003	Study on the efficacy and attractivity of a wheat bait at 50 mg/kg of chlorophacinone in the rat, *Rattus Norvegicus*, wild strain, sensitive to coumafene. Laboratoire de Toxicologie, ENVL, laboratory report no. RE/0302/CPN/Wheat/Rn/S/T0, June 2003 (unpublished).	LiphaTech S.A.S.	☐	☒	☒	☐
IIIB 5.10.3		Berny, P.	2003	Study on the efficacy and attractivity of an impregnated wheat bait with 50 mg/kg of chlorophacinone in the house mouse, *Mus musculus*, wild strain, sensitive to warfarin. Laboratoire de Toxicologie, ENVL, laboratory report no. RE/0303/CPN/Wheat/Mm/S/T0, June 2003 (unpublished).	LiphaTech S.A.S.	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB 5.10.8		Berny, P.	2012	Study on the efficacy and attractivity of a wheat at 50 mg/kg of chlorophacinone in the rat, *Rattus Norvegicus*, wild strain, sensitive to warfarin. Laboratoire de Toxicologie, ENVL, laboratory report no. RE/1203/CPN/Wheat/Rn/S. April 2012 (unpublished).	LiphaTech S.A.S.	☐	☒	☒	☐
IIIB 6.1.1-01		Myers, R.C. and Christopher, S.M.	1993 a	Rozol® Pellets: Acute Peroral Toxicity Study in the Rat. Bushy Run Research Center. Laboratory report no. 93N1275 GLP/Unpublished	LiphaTech	☐	☒	☒	☐
IIIB 6.1.2-01		Glaza, S.M.	1995 a	Acute Dermal Toxicity Study (Limit Test) of Rozol® Pocket Gopher Bait in Rabbits. Hazleton Wisconsin, Madison, Wisconsin, USA. Laboratory report no. HWI 41200819 GLP/Unpublished	LiphaTech	☐	☒	☒	☐
IIIB 6.1.2-02		Parker, R.M.	1992	Dermal limit study of Rozol® Paraffinised Pellets administered to New Zealand White Rabbits. TSI Redfield Laboratories. Laboratory report no. 008-0005 GLP/Unpublished	LiphaTech	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB 6.2-01		Glaza, S.M.	1995 b	Primary Dermal Irritation Study of Rozol® Pocket Gopher Bait in Rabbits. Hazleton Wisconsin, Madison, Wisconsin, USA. Laboratory report no. HWI 41200820 GLP/Unpublished	LiphaTech	☐	☒	☒	☐
IIIB 6.2-02		Glaza, S.M.	1995 c	Primary Eye Irritancy Study Rozol® Pocket Gopher Bait in Rabbits. Hazleton Wisconsin, Madison, Wisconsin, USA. Laboratory report no. HWI 41200821 GLP/Unpublished	LiphaTech	☐	☒	☒	☐
IIIB 6.2-03		Myers, R.C. and Christopher, S.M.	1993 b	Rozol® Pellets: Cutaneous Irritancy Testing using the Rabbit. Bushy Run Research Center. Laboratory report no. 93N1306A GLP/Unpublished	LiphaTech	☐	☒	☒	☐
IIIB 6.2-04		Myers, R.C. and Christopher, S.M.	1993 c	Rozol® Pellets: Ocular Irritancy Testing using the Rabbit. Bushy Run Research Center. Laboratory report no. 93N1306B GLP/Unpublished	LiphaTech	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB 6.3-01		Glaza, S.M.	1995 d	Dermal sensitization Study of Rozol® Pocket Gopher Bait in Guinea Pigs – Closed patch Technique. Hazleton Wisconsin, Madison, Wisconsin, USA. Laboratory report no. HWI 41200822 GLP/Unpublished	LiphaTech	☐	☒	☒	☐
IIIB 6.3-02		Myers, R.C. and Christopher, S.M.	1994	Rozol® Pellets: Dermal Sensitization Study in the Guinea Pig Using the Buehler Technique. Laboratory report no. 93N1307. GLP/Unpublished	LiphaTech	☐	☒	☒	☐
IIIB 6.4-01		Hardwick, T. and Russell, N.	2003	[^{14}C]-Chlorophacinone: Rates of penetration through human skin using a flow through in vitro system. Covance Laboratories Ltd. laboratory report number 2336/002-D1145. GLP/Unpublished	LiphaTech	☐	☒	☒	☐
Add rows as necessary									

Annex 3: Analytical methods residues – active substance

Chlorophacinone

Date: 22.06 .2012

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products			
food of animal origin			
soil			
drinking water			
surface water			
air			
body fluids / tissues			

Methods suitable for the determination of residues (monitoring methods)

Test substance	Sample	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of determination	Reference
						Range	Mean	RSD %		
Chlorophacinone	soil	LC/MS-MS	0.01 to 0.10 mg/kg / 10	r^2 = 0.9939	specific	85 - 102	94	5.4	0.01 mg/kg	A4.2(a)/01
	air	LC/MS-MS	0.03 to 0.3 µg/m3 / 20	r^2 = 0.9968	specific	71 - 100	83 - 88	10.1 - 11.2	0.03 µg/m^3	A4.2(b)/01
	drinking water	LC/MS-MS	0.05 to 0.50 µg/L /10	r^2 = >0.9960	specific	79 - 107	96	11.2	0.05 µg/L	A4.2(c)/01
	surface water	LC/MS-MS	0.05 to 0.50 µg/L /10	r^2 = >0.9960	specific	71 - 103	87	10.9	0.05 µg/L	A4.2(c)/01
	blood	LC/MS-MS	0.05 to 0.50 mg/L /10	r^2 = 0.985	specific	69 - 82	76	6.4	0.05 mg/L	A4.2(d)/01
	liver	LC/MS-MS	0.05 to 0.50 mg/kg /10	r2 = 0.9903	specific	57 - 126	82	27.7	0.05 mg/kg	A4.2(d)/02

Annex 4: Toxicology and metabolism –active substance

Chlorophacinone

Threshold Limits and other Values for Human Health Risk Assessment

Date: 22/06/2012

Summary			
	Value	Study	SF
AEL long-term	0.000017 mg/kg bw/d	90-day study in rat	300
AEL medium-term	0.000017 mg/kg bw/d	90-day study in rat	300
AEL acute	0.000033	Teratogenicity study in rabbit	300

Inhalative absorption	100%
Oral absorption	100%
Dermal absorption	1,7%

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Current classification T+ R27/28 T R23-R48/24/25; N, R50/53
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Current classification Acute Tox Cat 1 H310 Acute Tox Cat 2 H300 Acute Tox Cat 3 H331 STOT RE Cat 1 H372

CAID GRAIN'TECH

Date: 22/06/2012

General information
Formulation Type : grain bait
Active substance(s) (incl. content): 0.005% chlorophacinone

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	> 5 000 mg/kg bw
Rat LD50 dermal (OECD 402)	> 2 000 mg/kg bw
Rat LC50 inhalation (OECD 403)	no study submitted
Skin irritation (OECD 404)	non irritant
Eye irritation (OECD 405)	non irritant
Skin sensitisation (OECD 429; LLNA)	not sensitizing

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	None
Toxicological data on active substance(s) (not tested with the preparation)	None
Toxicological data on non-active substance(s) (not tested with the preparation)	None
Further toxicological information	None

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	None
Regulation 1272/2008/EC	none

CAID GRAIN'TECH

Date: 22/06/2012

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure of professionals – CAID GRAIN' TECH in bulk (exposure during decanting, loading and cleaning considered) – Control of rats an mice

	Component	CAS	Actual Dermal Total [mg/kg/d]	Inhalation Exposure [mg/m³]	Model
Professionnal users					
Professionnal rat (without PPE)	Chlorophacinone	3691-35-8	$5.8x10^{-6}$	$8.3x10^{-6}$	Cefic study
Professionnal mice (without PPE)	Chlorophacinone	3691-35-8	$6.9x10^{-6}$	$5.5x10^{-6}$	Cefic study

Primary exposure of professionals – CAID GRAIN'TECH in sachet (exposure only during cleaning) – Control of rats and mice

	Component	CAS	Actual Dermal Total [mg/kg/d]	Inhalation Exposure [mg/m³]	Model
Professionnal rat (without PPE)	Chlorophacinone	3691-35-8	$8.6x10^{-6}$	Not applicable	Cefic study
Professionnal mice (without PPE)	Chlorophacinone	3691-35-8	$8.6x10^{-6}$	Not applicable	Cefic study

Risk assessment – Control of rats

Scenario	Component	CAS	AEL [mg/kg/d]	Absorption [%]		Total syst exposure [mg/kg bw/d]		Risk
				inh	derm	Expo	%AEL	
CAID GRAIN'TECH in bulk								
Professional (without gloves)	Chlorophacinone	3691-35-8	$1.7x10^{-5}$	100	1.7	$8.3x10^{-6}$	48.8	Acceptable
CAID GRAIN'TECH in sachet								
Professional (without gloves)	Chlorophacinone	3691-35-8	$1.7x10^{-5}$	100	1.7	$8.6x10^{-7}$	5.05	Acceptable

Risk assessment – Control of mice

Scenario	Component	CAS	AEL [mg/kg/d]	Absorption [%]		Total syst exposure [mg/kg bw/d]		Risk
				inh	derm	Expo	%AEL	
CAID GRAIN'TECH in bulk								
Professional (without gloves)	Chlorophacinone	3691-35-8	$1.7x10^{-5}$	100	1.7	$6.9x10^{-6}$	40.8	Acceptable
CAID GRAIN'TECH in sachet								
Professional (without gloves)	Chlorophacinone	3691-35-8	$1.7x10^{-5}$	100	1.7	$8.6x10^{-7}$	5.05	Acceptable

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

CAID GRAIN'TECH

Date:22/06/2012

General information	
Formulation Type	Grain bait
Active substance(s) (incl. content)	Chlorophacinone (0.005%)

<Chlorophacinone>

Data base for exposure estimation	
according to	Appendix: Toxicology and metabolism – active substance/CAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	non-professional use
Secondary exposure, acute	child ingesting bait
Secondary exposure, chronic	none

Conclusion:
Exposure of non-professionals to the biocidal product containing chlorophacinone as active substance is considered acceptable.

The accidental ingestion of baits poses a risk to infants since the AEL is exceeded when infant ingests more than 6.6 mg of product per day.

Details for the exposure estimates:

Primary exposure of non professionals – CAID GRAIN' TECH in bulk (loading and cleaning considered) – Control of rats an mice

Non professional users					
Non Professionnal rat (without PPE)	Chlorophacinone	3691-35-8	$6.24x10^{-7}$	negligible	Cefic study
Non Professionnal mice (without PPE)	Chlorophacinone	3691-35-8	$6.24x10^{-7}$	negligible	Cefic study

Primary exposure of non professionals – CAID GRAIN'TECH in sachet (exposure only during cleaning) – Control of rats and mice

	Component	**CAS**	**Actual Dermal Total [mg/kg/d]**	**Inhalation Exposure [mg/m³]**	**Model**

Non Professionnal rat (without PPE)	Chlorophacinone	3691-35-8	$3.2x10^{-7}$	Not applicable	Cefic study
Non Professionnal mice (without PPE)	Chlorophacinone	3691-35-8	$3.2x10^{-7}$	Not applicable	Cefic study

Risk assessment – Control of rats

Scenario	**Component**	**CAS**	**AEL [mg/kg/d]**	**Absorption [%]**		**Total syst exposure [mg/kg bw/d]**		Risk
				inh	derm	Expo	%AEL	
CAID GRAIN'TECH in bulk								
Non Professional (without gloves)	Chlorophacinone	3691-35-8	$1.7x10^{-5}$	100	1.7	$6.2x10^{-7}$	3.67	Acceptable
CAID GRAIN'TECH in sachet								
Non Professional (without gloves)	Chlorophacinone	3691-35-8	$1.7x10^{-5}$	100	1.7	$3.2x10^{-7}$	1.88	Acceptable

Risk assessment – Control of mice

Scenario	**Component**	**CAS**	**AEL [mg/kg/d]**	**Absorption [%]**		**Total syst exposure [mg/kg bw/d]**		Risk
				inh	derm	Expo	%AEL	
CAID GRAIN'TECH in bulk								
Non Professional (without gloves)	Chlorophacinone	3691-35-8	$1.7x10^{-5}$	100	1.7	$6.2x10^{-7}$	3.67	Acceptable
CAID GRAIN'TECH in sachet								
Non Professional (without gloves)	Chlorophacinone	3691-35-8	$1.7x10^{-5}$	100	1.7	$3.2x10^{-7}$	1.88	Acceptable

Chlorophacinone

The intended use descriptions of the chlorphacinone-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. No further data are required concerning the residue behaviour. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff.

Annex 9: Efficacy of the active substance from its use in the biocidal product (*)

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference	R.I
Red grain (CAID GRAIN'TECH) LR191	Rat *Rattus norvegicus* (wild strain, sensitive to coumafene)	Laboratory study, using bait aged for 3 month, one free-choice test with a total of 10 mixed sex animals, 5 days exposure.	Palatability of the treated bait was greater than that of the reference diet (0.57). Efficacy was 100% occurring between 5 and 15 days after initial consumption.	IIIB5.10.2-01	1
Red grain (CAID GRAIN'TECH) LR191	Rat *Rattus norvegicus* (wild strain, sensitive to coumafene)	Laboratory study, using bait aged for 3 month, one free-choice test with a total of 10 mixed sex animals, 5 days exposure.	Palatability of the treated bait was equivalent to or similar to the reference diet (0.47). Efficacy was 100% occurring between 5 and 8 days after initial consumption.		
Red grain (CAID GRAIN'TECH) LR191	Rat *Rattus norvegicus* (wild strain, sensitive to coumafene)	Laboratory study, using fresh bait, one free-choice test with a total of 10 mixed sex animals, 4 days exposure.	Palatability of the treated bait was greater than the reference diet in the test (0.48). Efficacy was 90% occurring between 4 and 10 days after initial consumption.	IIIB5.10.2-02	1
Red grain (CAID GRAIN'TECH) LR191	Rat *Rattus norvegicus* (wild strain, sensitive to coumafene)	Laboratory study, using fresh bait, one free-choice test with a total of 22 mixed sex animals, 4 days exposure.	Palatability of the treated bait was equivalent to or similar to that of the reference diet in each test (0.4). Efficacy was 90% occurring between 7 and 17 days after initial consumption.		

Red grain (CAID GRAIN'TECH) LR0191	Mouse *Mus musculus* (wild strain, sensitive to warfarin)	Laboratory study, using bait aged for 1 month, one free-choice test with a total of 22 mixed sex animals, 4 days exposure.	Palatability of the treated bait was superior to that of the reference diet (0.90). Efficacy was 96% occurring between 5 and 11 days after initial consumption.	IIIB5.10.2-03	1
Red grain (CAID GRAIN'TECH) LR0191	Rat *Rattus norvegicus* (wild strain, sensitive to warfarin)	Laboratory study, using bait aged for 42 months, one free-choice test with a total of 10 mixed sex animals, 4 days exposure	Palatability of the treated bait was superior to that of the reference diet (0.66). Efficacy was 100% occurring between 9 and 17 days after initial consumption.	IIIB5.10.2-08	1
Red block F00507	Rat *Rattus rattus* (wild strain, sensitive to warfarin)	Laboratory study, using bait aged 20 month, one free choice test with a total of 10 mixed sex animals, 4 days exposure	Palatability of the treated bait was superior to that of the reference diet (0.64). Efficacy was 90% occurring between 7 and 14 days after initial consumption.	IIIB5.10.2-01	1
Red block F00507	Rat Rattus rattus (wild strain, sensitive to warfarin)	Laboratory study, using bait aged 20 month, one free choice test with a total of 10 mixed sex animals, 4 days exposure	Palatability of the treated bait was superior to that of the reference diet (0.51). Efficacy was 90% occurring between 7 and 14 days after initial consumption.		

Addendum to the Product Assessment Report

Biocidal product assessment report related to product authorisation under Regulation (EU) No 528/2012

CAID GRAIN'TECH

LIPHATECH SAS

March 2015

Internal registration/file no:	2011/4329/11206/FR/AA/20567
Authorisation/Registration no:	FR-2013-0002 (professional) and FR-2013-1001 (non-professionnal)
Granting date/entry into force of authorisation/ registration:	4th of March, 2013
Expiry date of authorisation/ registration:	30th of june, 2016
Active ingredient:	Chlorophacinone
Product type:	14 - Rodenticide

Competent Authority in charge of delivering the product authorisation:
French Ministry of Ecology
Department for Nuisance Prevention and Quality of the Environment
Chemical Substances and Preparation Unit
Tour Séquoia
92 055 La Défense cedex – FRANCE
autorisation-biocide@developpement-durable.gouv.fr

Authority in charge of the efficacy and risk assessment:
Anses – French agency for food, environmental and occupational health and safety
Regulated Products Directorate
14 rue Pierre et Marie Curie
94 701 Maisons-Alfort cedex - FRANCE
biocides@anses.fr

1. General information

This addendum relates to the discussions at European level that took place in the frame of a referral of disagreement on mutual recognition by a concerned Member State under Article 35 of Regulation (EU) No 528/2012.

2. Summary of the product assessment

This section only refers to the discussions at European level that took place in the frame of a referral of disagreement on mutual recognition by a concerned Member State under Article 35 of Regulation (EU) No 528/2012.

For further details regarding the initial assessment of this product, please refer to the product assessment report related to CAID GRAIN'TECH product authorization under Directive 98/8/EC.

2.5 Effectiveness

In the frame of a referral of disagreement on mutual recognition by a concerned Member State under Article 35 of Regulation (EU) No 528/2012, the efficacy assessment carried out by the French technical agency (Anses) has been challenged.

Based on the discussions at European level that took place in the frame of the Coordination Group, an agreement was reached on the 13rd of May 2014 between the reference member state and the initiating concerned member state. This agreement introduced a condition for the applicant to provide a study (bait choice test) demonstrating the efficacy against the target organism *Rattus rattus* within a given time frame of 6 months.

Considering that no data have been submitted to Anses after this 6 months' time frame, the efficacy of the product against the target organism *Rattus rattus* is challenged, and the use of the product against this target species cannot be authorised anymore.

Furthermore, due to regional specificity, Anses considers that for the claim "use against rats", efficacy must be shown on both species *Rattus rattus* and *Rattus norvegicus*. So, in the absence of supporting data to validate the efficacy of the product against *Rattus rattus*, the efficacy of CAID GRAIN'TECH against Rattus norvegicus is also challenged and cannot be authorized anymore.

3. Decision

In the absence of the efficacy data for which an agreement was reached, the product CAID GRAIN'TECH can no longer be authorized for it use against rats (*Rattus rattus* and *Rattus norvegicus*). The decision dated 25/03/2015 reflects these changes. All same biocidal products linked to this reference product are updated accordingly.

The previous conclusions regarding risk assessment remain unchanged.