Product Assessment Report_rev

Fast Action Mouse Killer

October 2014

Internal file n.º:	03/2011-APB-2011/2369/10806/PT/AA/17125
Authorisation n.º:	PT/DGS APB-3/2014
Granting date/entry into force of authorisation:	22/10/2014
Expiry date of authorisation:	30/06/2021
Active ingredient:	Chloralose
Product type:	PT 14 rodenticides

Biocidal product assessment report related to product authorisation under Regulation (EU) n. º 528/2012

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1 General information about the product application

1.1 Applicant

Company Name:	Rentokil Initial 1927 plc
Address:	Rentokil Initial European Technical Centre, 7&8 Foundry Court, Foundry Lane
City:	Horsham
Postal Code:	RH13 5PY
Country:	United Kingdom
Telephone:	+44 (0) 1403 214 119
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1.1.1 Person authorised for communication on behalf of the applicant

Name:	Keira Corrie
Function:	Regulatory Manager
Address:	Rentokil Initial European Technical Centre, 7&8 Foundry Court, Foundry Lane
City:	Horsham
Postal Code:	RH13 5PY
Country:	United Kingdom
Telephone:	+44 (0) 1403 214 122
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1.2 Current authorisation holder

Company Name:	Rentokil Portugal - Serviços de Protecção Ambiental, Unipessoal, Lda.
Address:	Complexo Industrial de Vialonga - Fracção C1 e C2
City:	Granja de Alpriate
Postal Code:	2625-000 PÓVOA DE SANTA IRIA
Country:	Portugal
Telephone:	-
Fax:	-
E-mail address:	-
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	Not applicable

1.3 Proposed authorisation holder

Company Name:	Rentokil Initial 1927 plc
Address:	Rentokil Initial European Technical Centre, 7&8 Foundry Court, Foundry Lane
City:	Horsham
Postal Code:	RH13 5PY
Country:	United Kingdom
Telephone:	+44 (0) 1403 214 122
Fax:	+44 (0) 1403 214 101
E-mail address:	keira.corrie@rentokil-initial.com
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	Not applicable

1.4 Information about the product application

Application received:	26/06/2011
Application reported complete:	15/02/2013
Type of application:	Product authorisation
Further information:	

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Fast Action Mouse Killer
Manufacturer's development code number(s), if appropriate:	Not applicable. There is no manufacturer's development code number.
Product type:	PT 14 Rodenticide
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Chloralose 4%
Formulation type:	Two Solid Bait Blocks in Tamper Resistant Bait Box
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**	No

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, Alphakil Block/Alphablock

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	For indoor control of mice
Target organisms:	House mouse *(Mus musculus domesticus)* juveniles and adults
Category of users:	V.1 non-professional / general public.
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:	The product is for single use only, ready and easy to use. Simply place the box where mice have been seen. Ideal locations are against walls, under cupboards or behind furniture (where they cannot be tampered with). When using both boxes, place them 3 metres apart. Bait boxes should only be placed for a maximum of 7-10 days. Once the mouse infestation is controlled, do not place further bait box until a new infestation is identified. In some unusual situations, if mouse activity remains, it may be necessary to try another means of control.
Potential for release into the environment (yes/no):	No
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	See point 2.2.2.
Use Restrictions:	For indoor use only, in tamper resistant bait box, with nominal concentration of the active substance in the products of 40 g/kg, containing an aversive and a dye.

1.5.3 Information on active substance(s)[1]

Active substance chemical name:	(R)-1,2-O-(2,2,2-Trichloroethylidene)-α-D-glucofuranose
CAS No:	15879-93-3
EC No:	240-016-7
Purity (minimum, g/kg or g/l):	825 g/kg
Inclusion directive:	Commission Directive 2009/93/EC of 31st July 2009
Date of inclusion:	1st July 2011

[1] Please insert additional columns as necessary

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:	Physalys sarl
Address:	3 rue de l'arrivée – BP 215
City:	Paris
Postal Code:	F.75749 Paris Cedex 15
Country:	France
Telephone:	+33 1 4321 7062
Fax:	+33 1 4321 7063
E-mail address:	ybassat@club-internet.fr

1.5.4 Information on the substance(s) of concern

No chemical substances included in the formulated product are considered to be of toxicological concern in view of their toxicity profile except Bitrex, a human taste deterrent. Bitrex is present in a 2.5% aqueous solution which is present in the product at 0.4% giving a final concentration of 0.01% of Bitrex in the product. At this concentration no toxicological concern is considered.

1.6 Documentation

1.6.1 Data submitted in relation to product application

Additional data on storage stability and efficacy of the product have been included to support the application for product authorisation.

A new study regarding relative self-ignition temperature determination on chloralose has been submitted. These studies are listed in Annex 2.

1.6.2 Access to documentation

The applicant has submitted a letter of access signed by the sole Authorised Signatory for this purpose in the Company Physalys sarl granting to ««the Competent Authority in Portugal the right to refer to and use the Physalys proprietary data held on the active substance Alphachloralose and the Representative Products included in the Application for Annex I listing under 98/8/EC, plus the submitted additional supplementary information, on behalf of the beneficiary Company, Rentokil Initial 1927 plc.

This provision of access to this data is subject to Rentokil Initial 1927 plc's compliance with the Dossier Agreement and New Supply Agreement between Rentokil Initial UK Limited and Physalys sarl entered into on 15 June 2011 and solely for the purpose of its use by" Competent Authority in Portugal "in the evaluation for Biocidal Product Authorisation in Portugal, under the requirements of 98/8/EC, of the Rentokil product to be Authorised as Fast Action Mouse Killer, (for amateur users)»».

2 Summary of the product assessment

2.1 Identity related issues

Fast Action Mouse Killer consists of a plastic tamper resistant outer box which is pre-baited with two solid bait blocks prior to market for non-professional / general public use. Boxes are for single use only. Each block weighs 5g; there are two blocks per box giving a total of 10g per box. The active substance is present at 4% w/w resulting in 0.4g of chloralose per bait box.

The manufacturer and manufacturing site for the production of chloralose used in Fast Action Mouse Killer are the same as the ones evaluated during Annex I inclusion of the active substance chloralose, so there are no issues raised related to technical equivalence of active substance.

Composition of the product is presented in table below.

Fast Action Mouse Killer	**% m/m**	**Function**
Chloralose	4.000	Active substance
Bitrex 2.5% Aqueous Solution	0.400	Taste aversant
Other components	Up to 100	See SPC

For detailed quantitative information on the composition of the biocidal product, please refer to SPC document.

Fast Action Mouse Killer presents a similar composition as the representative biocidal product Alphakil Block, evaluated during Annex I inclusion.

The only difference between both formulations is the amounts of the fats they contain. Considering the similarity in composition and the same type of use, the RMS considers that evaluation performed for Annex I inclusion regarding product Alphakil Block can be used in Fast Action Mouse Killer assessment.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

Conventional method used for biocidal product classification.

Chloralose has been classified by RMS, for Annex I inclusion on BPD purposes as:

Xn - R20/22 – Harmful by inhalation and if swallowed
N - Dangerous for the environment;
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

A dossier for harmonised classification and labelling of chloralose according to Regulation (EC) n. º 1272/2008 is under evaluation.

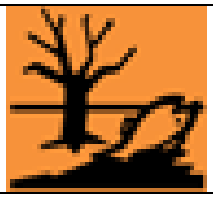
Classification according to Directive 1999/45/EC
N: Dangerous for the environment
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Classification according to Regulation (EC) n. º 1272/2008 (CLP Regulation)

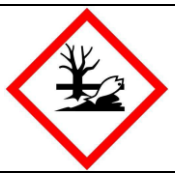
Acute Aquatic Category 1
Chronic Aquatic Category 1
H400: Very toxic to aquatic life
H410: Very toxic to aquatic life with long lasting effects.

2.2.2 Labelling of the biocidal product

Labelling according to Directive 1999/45/EC

Symbol(s):	
Indication(s) of danger:	N: Dangerous for the environment
Risk phrases:	R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases:	S2 - Keep out of the reach of children S13 - Keep away from food, drink and animal feedingstuffs. S20/21 - When using do not eat, drink or smoke. S35 - This material and its container must be disposed of in a safe way. S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S61 – Avoid release to the environment. Refer to special instructions / safety data sheet.

Labelling according to Regulation (EC) n.º 1272/2008 (CLP Regulation)

Pictograms	
Signal word	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects.
Precautionary Statement	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read label before use. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P501: Dispose of contents/container in accordance with local requirements.

In addition, the label must show clearly and indelibly the following information:

- labels shall not be misleading or give an exaggerated impression of the product and, in any case, do not mention the indications ‘low-risk biocidal product’, ‘non-toxic’, ‘harmless’, ‘natural’, ‘environmentally friendly’, ‘animal friendly’ or similar indications.

- identity of the active substance and its concentration in metric units: chloralose 4% w/w.

- authorisation number: PT/DGS APB-3/2014.

- name, address and telephone number of the authorisation holder: Rentokil Initial 1927 plc - Rentokil Initial European Technical Centre, 7&8 Foundry Court, Foundry Lane - Horsham - RH13 5PY UNITED KINGDOM. Telephone: +44 (0) 1403 214 122.

- type of formulation: Two green solid bait blocks in tamper resistant bait box.

- uses for which the biocidal product is authorized: rodenticide for house mice *(Mus musculus domesticus)*, juveniles and adults.

- directions for use, frequency of application and dose rate: Simply place the bait box where mice have been seen. Ideal locations are against walls, under cupboards or behind furniture (where they cannot be tampered with). When using both boxes, place them a few metres apart. Once the mouse infestation is controlled, do not place further bait box until a new infestation is identified. Bait boxes can remain in place for a maximum of 7-10 days. In some unusual situations, if mouse activity remains, it may be necessary to try another means of control of bait.

- likely direct or indirect adverse side effects and any directions for first aid: Ingestion of the product in large quantities may lead to nausea, vomiting, nervous system depression, headache and weakness leading to unconsciousness.
  General Advice:
  In the event of accidental consumption the patient should be kept quiet and warm and a doctor called. Airways should be kept clear. Avoid sedatives. If cats or dogs are affected, similar first aid treatment should be employed.
  For further information, contact the National Poison Information Centre. In Portugal (CIAV) - tel: 808 250 143 or contact 112. Retain the label for reference.
  Advice for Doctors:
  Treatment is symptomatic and there is no specific antidote.

- if product accompanied by a leaflet, the sentence: ‘Read attached instructions before use’.

- directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging: Remove all bait boxes after treatment and dispose of in accordance with local requirements. Bait boxes must not be reused or recycled.

- formulation batch number.

- expiry date relevant to normal conditions of storage: 2 years, from manufacturing date.

- cleaning of equipment: Not applicable.

- categories of users: V.1 non-professional / general public.

- information concerning protection of non-target organisms: Keep out of the reach of children and companion animals; Keep away from food, drink and animal feedingstuffs.

- information concerning protection of environment: Avoid release to the environment; Keep away from drains, surface and ground water, and soil; DO NOT contaminate watercourses or ground.

2.2.3 Packaging of the biocidal product

Fast Action Mouse Killer (which is itself a tamper resistant bait box containing 2 x 5g blocks of triangular shape with height approximately 1cm) will be supplied in a cardboard box containing 2 tamper resistant bait boxes.

2.3 Physico/chemical properties and analytical methods

2.3.1 Physico-chemical properties

Physico-chemical properties of the active substance

Chloralose does not exhibit hazardous physical-properties. It is a white to yellowish white powder with no discernible odour and with a melting point of 176.6ºC. It is slightly volatile, has a low vapour pressure (0.0083 Pa at 25ºC), and a low Henry's Law constant. It is readily soluble in water, soluble in organic solvents; it is thermally stable, not flammable and should not be considered to have explosive or oxidising properties.

There is no specific packaging material which is known to be incompatible with chloralose.

A new study regarding relative self-ignition temperature determination on chloralose has been submitted. This test was performed according to EC Testing Method A16.

The relative self-ignition temperature of the sample is defined as the temperature of the oven at which the sample temperature reaches 400ºC by self-heating. The sample of chloralose was observed to undergo an endothermic event (possibly melting) from 166ºC. No self-heating of the sample was observed during the test.

Physico-chemical properties of the biocidal product

Table 2: Physico-chemical properties of the biocidal product:

	Method	**Purity/Specification**	**Results**	**Reference**
Physical state and nature	Solid block	-	-	-
Colour	Green	-	-	-
Odour	No perceptible odour	-	-	-
Explosive properties	Not tested. Waiving based on physical properties of components	Not applicable	None of the components of Fast Action Mouse Killer are classified as explosive and all are stable under normal conditions	Waiving accepted based on data regarding all components of the product
Oxidizing properties	Not tested. Waiving based on physical properties of components	Not applicable	None of the components of Fast Action Mouse Killer are classified as oxidising and all are stable under normal conditions	Waiving accepted based on data regarding all components of the product
Flash point	Not tested. Waiving based	Not applicable	None of the components of Fast	Waiving accepted based

	Method	Purity/Specification	Results	Reference
	on physical properties of components		Action Mouse Killer are classified as flammable and all are stable under normal conditions	on data regarding all components of the product
Autoflammability	See flash point	See flash point	See flash point	See flash point
Other indications of flammability	See flash point	See flash point	See flash point	See flash point
Acidity / Alkalinity	Not tested. Waiving based on physical properties of the product	Not applicable	Fast Action Mouse Killer is a solid fat based product thus a 1% aqueous solution, an emulsion or dispersion cannot be made and therefore the acidity/alkalinity of the products cannot measure. The pH of the active substance is approximately pH 7.	Waiving accepted
Relative density / bulk density	Not tested. Waiving based on physical properties of the product	Not applicable	Fast Action Mouse Killer is a fat based solid block therefore does not meet the criteria for requiring relative density to be measured	Waiving accepted
Storage stability – stability and shelf life				
Accelerated shelf life	Four packs of Fast Action Mouse Killer were used for the test. Two packs were analysed for α- and ß-chloralose content in the bait. The other two packs were placed in an oven at 54 ºc for 2 weeks. The appearance of the samples was then recorded and the samples analysed for α- and ß-chloralose GLP Each Pack consists of outer cardboard box, two plastic bait boxes and	Test run on Fast Action Mouse Killer	Alpha-chloralose Initial: 3.34 %m/m. Alpha-chloralose Aged: 3.59 %m/m. Beta-chloralose Initial: 0.47 % m/m. Beta-chloralose Aged: 0.47% m/m. The amount of alpha-chloralose increased slightly in the aged sample (+7.3%), although this is within the analytical tolerance of ±10%. Appearance: Pack 3 and Pack 4: Compared to Initial, the aged showed no change in appearance of outer packaging or bait boxes. Slight seepage of fat from the baits into the bait boxes. This slight seepage	Rentokil Initial 1927 plc. Rentokil European Technical Centre Analytical Services Report Project No.298/24. 15th March 2006. Accelerated Shelf Life: Fast Action Mouse Killer. Applicants reference number ALPHCHL-332.

	Method	Purity/Specification	Results	Reference
	pre-dosed bait in box		of fat from the bait on storage can be expected as the storage temperature is only just below the melting point of the bait. 2-week accelerated storage trials of Fast Action Mouse Killer samples show there was a slight loss in weight on storage of the sample, which can be expected on storage at elevated temperatures.	
Long-term storage stability, shelf life	Samples of Fast Action Mouse Killer were storaged for 24 months at ambient temperatures. After ageing, samples and pack were analysed to assess the performance of the product and its packaging. GLP Pack Type 4x5g blocks in 2x pre-baited polypropylene plastic boxes in outer cardboard box	Test run on Fast Action Mouse Killer	Alphachloralose initial: 3.627 % w/w Alphachloralose final: 3.401 % w/w Δ= -6.2% Beta-chloralose Initial: 0.553 % w/w Beta-chloralose final: 0.518% w/w Δ= -6.3% Levels of alpha-chloralose and beta-chloralose decreased, but are within the allowed variance of ±10% of FAO guidelines. There was no change in the integrity of the pack or appearance of the product during storage period.	Rentokil Initial 1927 plc. Rentokil European Technical Centre Study Report No.244/73. 27th June 2012. Storage stability – Fast Action Mouse Killer. Applicants reference number ALPHCHL-374
Effects of temperature	No effects observed in storage stability studies			
Effects of light	Not investigated			
Reactivity towards container material	No reactivity observed in storage stability studies			
Technical characteristics in dependence of the formulation type	Not tested. Waiving based on physical properties of the product	Not applicable	Fast Action Mouse Killer is a solid block ready for use so none of the technical characteristics is applicable.	Waiving accepted
Compatibility with other products	Not tested. Waiving based on type of use	Not applicable	Fast Action Mouse Killer, is a ready to use product. It is not designed to be used in conjunction with any other	Waiving accepted

	Method	Purity/Specification	Results	Reference
			product or active ingredient	
Surface tension	Not tested. Waiving based on physical properties of the product	Not applicable	Fast Action Mouse Killer is supplied as a ready to use solid block	Waiving accepted
Viscosity	Not tested. Waiving based on physical properties of the product	Not applicable	Fast Action Mouse Killer is supplied as a ready to use solid block	Waiving accepted
Particle size distribution	Not tested. Waiving based on physical properties of the product	Not applicable	Fast Action Mouse Killer is supplied as a ready to use solid block therefore it is not necessary to measure particle size.	Waiving accepted

Fast Action Mouse Killer is supplied in a TRBB as a ready to use triangular shaped solid bait block based on food stuffs fit for human consumption, of green colour with no perceptible odour. None of the components of Fast Action Mouse Killer is classified regarding physic-chemical properties.

Label claim of two years shelf life provided by the applicant is supported by results of storage stability tests.

2.3.2 Analytical methods

	Principle of method
Technical active substance as manufactured:	The method consists of a dissolution of alphachloralose reference material in methanol followed by determination using HPLC with a 5 µm, 100Å, C-18, 250 x 3.0 mm column and with a photodiode array detector. The linearity and accuracy of the method were determined using external calibration solutions. LOQ is 5% (w/w).
Impurities in technical active substance:	The method consists of a dissolution of betachloralose reference material in methanol followed by determination using HPLC with a 5 µm, 100Å, C-18, 250 x 3.0 mm column and with a photodiode array detector. The linearity and accuracy of the method were determined using external calibration solutions. LOQ is 5% (w/w).
active substance in the formulation:	The method consists of sample dissolution in hexane, followed by partition into methanol. Determination is performed using HPLC with a 100 Å, 250 mm x 3.0 mm x 5 µm column.

An analytical method for determining the concentration of the active substance in the biocidal product was submitted and validated on the basis of linearity, accuracy, precision and specificity.
The method consists of sample dissolution in hexane, followed by partition into methanol. Determination is performed using HPLC with a 100 Å, 250 mm x 3.0 mm x 5 µm column.

Regarding alphachloralose the methods of analysis of the active substance, as manufactured, has been validated and shown to be sufficiently specific, accurate and precise. A method of analysis for the ß isomer, present at a quantity ≤ 15% w/w, was also validated.

A LC/MS/MS method was developed for the analysis of alphachloralose and betachloralose in surface water and drinking water with a limit of quantification of 0.1 µg/L.

A GC-MS method was submitted for the identification and quantification of residues of both isomers derivatised with Tri-Sil Z in soil, with a limit of quantification of 0.05 mg/kg.

Analytical methods for the determination of residues of alphachloralose derivatised with Tri-sil Z in/on food or feedingstuffs were developed. GC-MS and GC-ECD methods were used on cucumber, meat, oil-seed rape and lemon. A GC-ECD method was used on wheat. Validation parameters were only fulfilled for cucumber, therefore the tested methods are proposed to be used only for monitoring and control purposes.

Methods of analysis for relevant components and/or residue analysis in air, animal and human body fluids and tissues have not been submitted based on characteristics and use pattern of the product.

2.4 Risk assessment for Physico-chemical properties

Taking into account the available data, it can be concluded that Fast Action Mouse Killer does not pose any physical-chemical hazards.

2.5 Effectiveness against target organisms

2.5.1 Dose / mode of action / known limitations / resistance

Function

Fast Action Mouse Killer is a rodenticide (PT 14) based on chloralose for non-professional / general public users. It is intended to control House mouse (*mus musculus domesticus*) for indoor use only.

Mode of action

Chloralose is an acute central nervous system (CNS) depressant. It acts on the nervous system causing a depression in brain activity, slowing the heart and respiration. This leads to a reduction in body temperature, causing the mouse to die of hypothermia. Because mice are small they have a large surface area in relation to their volume from which to lose heat. Sleep is induced before death and mice can be unconscious within 15 minutes of eating bait, depending on temperature, although a short period of hyperactivity may sometimes occur.

Resistance

There are no reports of resistance to chloralose products found. Development of resistance doesn't seem to be an issue given that, provided a critical lethal dose is taken it kills rodents in a single dose. This means there is no mechanism for resistance to chloralose products to develop because target organisms are rarely exposed to sub-lethal concentrations of chloralose.

Resistance management strategy

Good pest control management principals should be employed which intrinsically reduce the likelihood of developing resistance. This involves 'integrated pest management' which incorporates

habitat management, control of rodent movement through proofing as well as control of the population using appropriate chemical and physical control measures. In general the normal procedure for reducing the development of resistance is to rotate the control agent chemical between different chemical types of rodenticide and it is recommended that this is done.

Humaneness

Convulsive effects prior to insensibility have been reported when using chloralose product as a rodenticide. Convulsions are suggestive of extreme distress but these occur in relatively few animals. According to human data these convulsions are of shorter duration and far less extreme, than those induced by strychnine. Animals that ingest non-lethal doses of chloralose rapidly recover. Regarding this, product can be considered to be a relatively humane rodenticide for control of mice.

Limitations

The toxicity can be affected by temperature with an increase in temperature reducing kill. Lund and Lodal (1977) found that with 4% chloralose kill rate was 100% at 15-16°C, between 90% and 40% kill at 16-20°C and between 30%-60% kill at 19-24°C. However chloralose has been used satisfactorily in high temperatures in Nigeria (Funmilayo (1982)).

Rentokil Initial 1927 plc have carried out efficacy trials on Alphablock at both 16° C and 21°C and found the product performs adequately at both temperatures. Summaries have been included below.

Efficacy Evaluation

For Annex I inclusion the applicant carried out several efficacy trials on Alphablock (4% w/w), at several temperatures, with *Mus domesticus,* Albino TO mice and Oakleaze wild mice (see table below).

New efficacy trials have been submitted at product approval stage.

Efficacy trials

Test Product	Test organisms	Test system / Concentrations applied / exposure time	Test Conditions	Test results: effects, mode of action, resistance	Reference
Alphablock 4% Chloralose	*Mus domesticus* Albino TO	After the period of acclimatisation (which as not less than 72h), the rodents were offered a choice between the test sample and an unpoisoned alternative bait (standard laboratory diet). Test and control baits were each supplied in approximately equal quantities. The positions of the test and control baits were interchanged daily. All test baits were removed at the end of the test period. Consumption of each bait was measured daily. Animals were also monitored daily for mortality or any signs of distress.	5 males, 5 females were used in each replicate. Each test mouse was weighed before test began. Weights of test animals were between 15-25g. Fresh samples at 16°C (+/- 2°C). Test period 4 days.	All animals died in 22 hours. Total intake: 17,7%	Weaver J S (2004), Palatability and Efficacy of Alphachloralose Mouse Bait Blocks (containning 2% and 4% Alphachloralose with 80 ppm Bitrex) vs. Albino TO Mice ("Low" Temperature) confidential
Alphablock 4% Chloralose	*Mus domesticus* Albino TO	After the period of acclimatisation (which as not less than 72h), the rodents were offered a choice between the test sample and an unpoisoned alternative bait (standard laboratory diet). Test and control baits were each supplied in approximately equal quantities. The positions of the test and control baits were interchanged daily. All test baits were removed at the end of the test period. Consumption of each bait was measured daily. Animals were also monitored daily for mortality or any signs of distress.	5 males, 5 females were used in each replicate. Each test mouse was weighed before test began. Weights of test animals were between 15-25g. Fresh samples at 16°C (+/- 2°C). Test period 4 days.	All animals died on the first day. Total intake: 25,3%	Weaver J S (2004), Initial Shelf-Life Trial of Alphachloralose Mouse Bait Blocks (Containing 4% Alphachloralose) confidential
Alphablock 4%	*Mus domesticus*	After the period of acclimatisation	5 males, 5 females were	The last mouse was dead 29	Weaver J S

Test Product	Test organisms	Test system / Concentrations applied / exposure time	Test Conditions	Test results: effects, mode of action, resistance	Reference
Chloralose	Albino TO	(which as not less than 72h), the rodents were offered a choice between the test sample and an unpoisoned alternative bait (standard laboratory diet). Test and control baits were each supplied in approximately equal quantities. The positions of the test and control baits were interchanged daily. All test baits were removed at the end of the test period. Consumption of each bait was measured daily. Animals were also monitored daily for mortality or any signs of distress.	used in each replicate. Each test mouse was weighed before test began. Weights of test animals were between 15-25g. Two week accelerated aged samples at 16°C (+/- 3°C). Test period 4 days.	½ hours after first presentation of the test baits. Total intake: 15,4%	(2004), Shelf-Life Bioassay of Acclerated Aged Alphachloralose Mouse Bait Blocks (4% Alphachloralose) at "Lowered" Temperature confidential
Alphablock 4% Chloralose	*Mus domesticus* Albino TO	After the period of acclimatisation (which as not less than 72h), the rodents were offered a choice between the test sample and an unpoisoned alternative bait (standard laboratory diet). Test and control baits were each supplied in approximately equal quantities. The positions of the test and control baits were interchanged daily. All test baits were removed at the end of the test period. Consumption of each bait was measured daily. Animals were also monitored daily for mortality or any signs of distress.	5 males, 5 females were used in each replicate. Each test mouse was weighed before test began. Weights of test animals were between 15-25g. Fresh samples at 21°C (+/- 2°C). Test period 4 days.	All animals died in 22 hours. Total intake: 41,1%	Weaver J S (2004), Palatability and Efficacy of Alphachloralose Mouse Bait Blocks (containing 2% and 4% Alphachloralose with 80 ppm Bitrex) vs. Albino TO Mice ("Room" Temperature) confidential
Alphablock 4% Chloralose	*Mus domesticus* Albino TO	After the period of acclimatisation (which as not less than 72h), the rodents were offered a choice between the test sample and an unpoisoned alternative bait (standard laboratory diet). Test and control baits were each supplied in approximately equal quantities. The	5 males, 5 females were used in each replicate. Each test mouse was weighed before test began. Weights of test animals were between 15-25g. Two week	All animals died on the first day. Total intake: 24,1%	Weaver J S (2004), Shelf-Life Bioassay of Acclerated Aged Alphachloralose Mouse Bait Blocks (4%

Test Product	Test organisms	Test system / Concentrations applied / exposure time	Test Conditions	Test results: effects, mode of action, resistance	Reference
		positions of the test and control baits were interchanged daily. All test baits were removed at the end of the test period. Consumption of each bait was measured daily. Animals were also monitored daily for mortality or any signs of distress.	accelerated aged samples at 21°C (+/- 2°C). Test period 4 days.		Alphachloralose) at "Room" Temperature confidential
Alphablock 4% Chloralose	*Mus domesticus* Oakleaze wild mice	Semi field trial. After the period of acclimatisation (which as not less than 72h), the rodents were offered a choice between the test sample and an unpoisoned alternative bait (standard laboratory diet). Test and control baits were each supplied in approximately equal quantities. The positions of the test and control baits were interchanged daily. All test baits were removed at the end of the test period. Consumption of each bait was measured daily. Animals were also monitored daily for mortality or any signs of distress. Trial performed with fresh samples, Wild-derived mice, group-housed in a pen.	3 male and 3 female mice used. The study was conducted in indoor pens. Each test mouse was weighed before test began. Weights of test animals were between 15-25g. Fresh samples of Alphablock were tested. Outside pen temperature was recorded daily, and ranged from 8°C to 14°C for the duration of the trial	After twenty one hours of the test period four out of six mice had succumbed to the bait. One was culled (as was expected to die in the next few hours because was exhibiting symptoms of poisoning: immobility and breathing in frequent large gasps), and the remaining mouse survived the trial. Total intake: 4,2%	Weaver J S (2004), Palatability and Efficacy of Alphachloralose Mouse Bait Blocks (containing 4% Alphachloralose) vs. Wild-Derived Mice confidential

Bait choice feeding trials demonstrate that the product has an acceptable palatability although overall bait intake is not always ≥ 20% of total intake. These results are due to the low uptake needed to induce death and to the fast acting nature of chloralose leading to death within few hours of ingestion. Nevertheless 100% of mortality is achieved in all trials regardless the use of fresh samples or accelerated aged samples.

New efficacy trials

Test Product	Test organisms	Test system / Concentrations applied / exposure time	Test Conditions	Test results: effects, mode of action, resistance	Reference
4% Alphchloralose Bait Blocks	House Mouse: *Mus domesticus*	Field trial The trial site was a plant nursery. The trial was conducted in two areas of this site, a stock room used to store bird feed, seeds and foodstuffs and the main shop area of the nursery which had a large area devoted to bulbs and also was used to display food items. In bait boxes (4% chloralose), in accordance with product label. Pre-census: 4 days. Lag Period: 4 days. Test Treatment: 17 days. Post Treatment Lag Period: 3 days. Post-treatment Bait Census: 4 days.	Treatment baits placed for 17 days. Up to 24 bait points used on site. Pre-treatment and post-treatment census bait, with tracking tiles. Weighing bait at bait points to indicate bait consumption. Intervals of examination: everyday for first week then longer intervals thereafter. The maximum tempera-ture was 16.0°C and the minimum was 7.0°C.	The post treatment census indicated a significant reduction in the rodent population with a 99.6% reduction in bait take between pretreatment and post-treatment census and a 100% reduction in tile score over the same period.	Rodenticide Efficacy Field Trial: Alphchloralose Bait Blocks (4% alphachloralose) against Mice at Orchard Nursery Data protection
4% Alphchloralose Bait Blocks	House Mouse: *Mus domesticus*	Field trial The trial site was a mountain biking and activity centre situated on farmland. The trial was conducted in the main building on the site which was used as a reception area for the park and as storage for bicycles. In bait boxes (4% chloralose), in accordance with product label. Pre-census: 3 days. Lag Period: 4 days. Test Treatment: 11 days.	Treatment baits placed for 11 days. Up to 24 bait points used on site. Pre-treatment and post-treatment census bait, with tracking tiles. Weighing bait at bait points to indicate bait consumption. Intervals of examination: everyday	The post treatment census indicated a significant reduction in the rodent population, with a 96.3% reduction in bait take. However the post treatment census tile score did not represent a complete decrease in mice numbers. The post treatment census tile score was 63.2% less than the pre-treatment census tile score.	Rodenticide Efficacy Field Trial: Alphchloralose Bait Blocks (4% alphachloralose) against Mice at Deers Leap Park Data protection

Test Product	Test organisms	Test system / Concentrations applied / exposure time	Test Conditions	Test results: effects, mode of action, resistance	Reference
		Post Treatment Lag Period: 3 days. Post-treatment Bait Census: 4 days.	for first week then longer intervals thereafter. The maximum temperature was 15.0°C and the minimum was 8.0°C.	Treatment bait take was initially relatively high. The bait take declined and then increased again over the treatment period and these fluctuations coincided with variations in tile scores. The continuing activity was most probably due to reinfestations of mice from surrounding properties.	
4% Alphchloralose Bait Blocks	House Mouse: *Mus domesticus*	Field trial The trial was carried out in the main farrowing unit of the pig farm. In bait boxes (4% chloralose), in accordance with product label. Pre-census: 4 days. Lag Period: 5 days. Test Treatment: 35 days. Post Treatment Lag Period: 5 days. Post-treatment Bait Census: 4 days.	Treatment baits placed for 35 days. Up to 50 bait points used on site. Pre-treatment and post-treatment census bait, with tracking tiles. Weighing bait at bait points to indicate bait consumption. Intervals of examination: everyday for first week then longer intervals thereafter. The maximum temperature was 19.0°C and the minimum was 1.0°C.	The post treatment census indicated a 70.2% reduction in bait take. Post treatment census tile score was 46.5% less than the pre-treatment census tile score. In the presence of many alternative food and possibly access to warmer conditions, the rapid initial mortality achieved by chloralose will slow and perhaps not achieve a more satisfactory result if left to continue.	Rodenticide Efficacy Field Trial: Alphchloralose Bait Blocks (4% alphachloralose) against Mice at Hetherdene Farm Data protection
4% Alphchloralose Bait Blocks	House Mouse: *Mus domesticus* (captive bred wild house mice of mixed sex and age)	Semi field trial. The treatment baits were placed inside the shed where the mice could easily access them. The same type of boxes were used as in the pre-treatment census and a control bait box containing alphachloralose blocks was placed in a	Thirty captive bred house mice were placed in a shed situated within a mouse proof pen and acclimatized for 72 hours prior to the trial starting. The shed and	All death mice collected were found in the first five days (19 on the first day, 5 on the second, 1 on the fourth and 1 on the fifth day) except for 1 which was found at the end of the trial period when	Rodenticide efficacy simulated field trial with acclimatisation: Alphachloralose Bait Blocks (4%

Test Product	Test organisms	Test system / Concentrations applied / exposure time	Test Conditions	Test results: effects, mode of action, resistance	Reference
		metal cage inside the shed. Treatment baits were in place for 11 days. Pre treatment census: 4 days. Lag Period: 3 days. Treatment: 11 days. Post Treatment Lag Period: 3 days. Pos treatment census: 4days.	pen contained harbourages suitable for mice, food and water. Conditions were intended to resemble a natural infestation of house mice within a building used for storage of animal feeds. Mice were free to move into and out of the shed from the pen area. During the trial the maximum temperature at ground level on the floor of the shed was 36.0°C and the minimum recorded temperature was 10.0°C. At the roof apex the maximum temperature was 49.0°C and the minimum temperature recorded was 11.0°C.	removing the shed. Bait take was reduced by 95.6% and tile score decreased by 100% from pre-treatment levels. Population reduction was 90% (27/30 mice) with 3 mice not found at the end of the trial.	alphachloralose) against captive bred house mice within pens at Rentokil Initial Research and Development Data protection
Alphchloralose Bait Blocks	House Mouse: *Mus domesticus* (captive bred wild house mice of mixed sex and age)	Semi field trial. The treatment baits were placed inside the shed where the mice could easily access them. The same type of boxes were used as in the pre-treatment census and a control bait box containing alphachloralose blocks was placed in a metal cage inside the shed. Treatment baits were in place for 11 days. Pre treatment census: 4 days. Lag Period: 3 days.	Thirty captive bred house mice were placed in a shed situated within a mouse proof pen. The shed and pen contained harbourages suitable for mice, food and water. Conditions were intended to resemble a natural infestation of house mice within a building used for	All of the dead mice collected were found in the first three days of the treatment period (20 on the first day, 7 on the second, one on the third). Two mice were still alive at the end of the 11 day trial. The post treatment census indicated a 86.2% reduction in bait take. Tile score stayed the same (0% decrease).	Rodenticide efficacy simulated field trial: Alphachloralose Bait Blocks (4% alphachloralose) against captive bred house mice within pens at Rentokil

Test Product	Test organisms	Test system / Concentrations applied / exposure time	Test Conditions	Test results: effects, mode of action, resistance	Reference
		Treatment: 11 days. Post Treatment Lag Period: 3 days. Pos treatment census: 4days.	storage of animal feeds. Mice were free to move into and out of the shed from the pen area. As soon as the mice had been released the pre-treatment census baits and tiles were placed within the shed. During the trial the maximum temperature at ground level on the floor of the shed was 37.0°C and the minimum recorded temperature was 10.0°C. At the roof apex the maximum temperature was 44.0°C and the minimum temperature recorded was 10.0°C.	Total mortality was 93%.	Initial Research and Development Data protection

Semi-field trials present levels of control of 83%, 90% and 93%. Low level obtained in one trial (83%) may be due to the low number of tested animal, only six mice.

Three field trials performed showed a reduction in bait take between pre-treatment and post-treatment census of 99.6%, 96.3% and 70.2% respectively.

The achieved level of control of 70.2% is below the acceptable level for field trials. This may result from situations with the presence of many alternative food and possibly access to warmer conditions. In these cases the rapid initial mortality achieved by chloralose will slow and perhaps not allow achieving a more satisfactory result if left to continue. Therefore, when a suitable level of initial mortality is achieved it is recommended to follow up with an alternative active ingredient (e.g. an anticoagulant) to treat any survivors after a period of one to two weeks.

Nevertheless the submitted data show that Fast Action Mouse Killer is efficacious in controlling house mouse *(Mus musculus domesticus).*

Evaluation of the label claim

Based on data submitted it can be concluded that Fast Action Mouse Killer is attractive, palatable and efficacious in controlling house mouse (*mus musculus domesticus*), at the proposed dose rate. Product permits an immediate reduction in infestation levels due to its ability to cause rapid initial mortality.

The label claim provided by the applicant is accepted.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Fast Action Mouse Killer is for non-professional / general public users and is intended to be used as a rodenticide (product type 14) for the control of house mouse (*Mus musculus domesticus*). This product does not require mixing, diluting or similar. In its use as a rodenticide, is presented as ready-to-use bait at a concentration of 4 % w/w, applied in a tamper resistant bait box, for indoor use only.

Fast Action Mouse Killer is a tamper resistant bait box (TRBB) ready and easy to use. Each tamper resistant bait box will contain 2 green, extruded bait blocks which gives 10g of bait and 0.4g of chloralose per box.

2.6.2 Assessment of exposure to humans and the environment

No new data or information has been submitted since the product applied for authorisation is identical to the representative product evaluated for Annex I inclusion of chloralose.

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the active substance was examined according to standard requirements.

Chloralose is an acute central nervous system (CNS) depressant. It acts on the nervous system causing a depression in brain activity, slowing the heart and respiration.

The end points for chloralose most relevant for risk characterisation purposes are listed below:

- oral LD50 (rat) of 341mg/kg, with CNS depression within 15 mins,
- dermal LD50 (rat) >2000mg/kg, no CNS depression (or other clinical signs) developed,
- inhalation LC50 (rat) > 1.99 mg/L,
- not irritant to eyes or skin,

- non-sensitiser,

- NOAELoral (28 days rat) of 20mg/kg bw/day based on CNS and body weight depression, and haematological changes at next dose level. CNS depression evident within 10-20 mins,

- NOAELoral (90 days rat) of 15mg/kg bw/day based on the critical effect of CNS depression observed at the next dose level,

- NOAELmaternal toxicity (rat and rabbit) of 15mg/kg bw/day based on CNS depression and alterations in body weight and food consumption at next dose level.

- NOAELfoetal toxicity (rat) of 15mg/kg bw/day based on reductions on body weight at next dose level. RMS considers these effects to be secondary to CNS depression. No teratogenic effects were observed,

− Chloralose tested negative in all three in vitro genotoxicity tests. Supporting evidence from two carcinogenicity (non guideline) studies with mice and dogs both concluded an absence of carcinogenicity potency for chloralose. There is no evidence of carcinogenicity or reproductive toxicity in humans despite therapeutic use and long follow-up time,

− Chloralose is rapidly absorbed, metabolized, and eliminated together with its metabolites and thus unlikely to bioaccumulate,

− Supporting evidence based on reading across from its main metabolite (chloral hydrate), in which the carcinogenicity potential of this metabolite was evaluated by the US-EPA, IPCS, IARC, and more recently WHO, 2005 found chloral hydrate to be carcinogenic in mice but not in rats. The evaluations of these organizations all stated that the potential carcinogenicity in mice (occurring only after hepatotoxicity is evident), is of highly questionable relevance to man. More recently, there is evidence that peroxisome proliferation is postulated as a mechanism of hepatic change with chloral hydrate. Since humans and other primates are less responsive than rats and mice in terms of peroxisomal proliferation, the rodent tumourigenicity of chloral hydrate is therefore of doubtful significance to man. Hence, RMS has no CMR concerns for chloral hydrate nor for chloralose.

2.7.1.2 Toxicology of the substance(s) of concern

The food grade components of the biocidal product are not classified.
Bitrex is present in the biocidal product at 0.01% a concentration that is not of toxicological concern.

2.7.1.3 Toxicology of the biocidal product

Fast Action Mouse Killer is based on food grade materials that are not classified. The only components of the product that are classified as hazardous for human health are the active ingredient, chloralose and the taste aversant Bitrex present in a concentration of 0.01%.

Using the conventional method those hazards do not carry through to the product thus Fast Action Mouse Killer is not classified as hazardous for health under EC Directive 1999/45 or CLP Regulation.

RMS considers that the information above provides adequate assurance and making separate testing on product involving further animal experiments are not necessary and would not provide any new information.

2.7.2 Exposure

The main paths of human exposure towards active substance from its use in biocidal product are:

Exposure path	Industrial use	Professional use	General public	Via the environment
Inhalation	N/A	Negligible	Negligible	Negligible
Dermal	N/A	Yes	Yes	Negligible
Oral	N/A	Negligible	Yes	Negligible

2.7.2.1 Exposure of professional users

Not applicable. Fast Action Mouse Killer is for non-professional / general public users.

2.7.2.2 Exposure of non-professional users and the general public

Exposure of non-professional users

Non-professional exposure during biocidal product use:

Intended use (MG/PT)	Exposure scenario	Inhalation uptake	Dermal uptake	Oral uptake
MG03: Pest control PT: 14 (rodenticide)	Preparation prior to application	N/A	N/A	N/A
	Loading bait into bait box, and placing box	N/A	Yes	N/A
	While in use	N/A	N/A	N/A
	Clean-up, bait disposal, and checking of bait.	N/A	Yes	N/A

Due to the non-volatile nature of chloralose and the nature of the formulation inhalation exposure is negligible and needs no further assessment. Oral exposure during normal non-professional use is unlikely, except if operator does not wash properly his/her hands after handling bait stations and dead mice. However, as the product contains the bittering agent, oral consumption will be greatly reduced and can be considered negligible with the intended use of the product and is not assessed further. Dermal exposure is the route of concern. The potential dermal exposure is presented in the table below.

Non-professional operator dermal exposure was estimated based on the default values and assumptions described in the TNsG, part 3, Appendix 7.2.1. These are summarised in the table below.

Loading bait into box	**Non-Professional Exposure (Fast Action Mouse Killer)**
Product per bait box	2 x 5g blocks = 10g
Daily amount of product used per operator	4 x 10g = 40g/day (4 boxes each with 2 blocks)

Amount of bait on hands per day (max 0.5% of applied amount) (*TNsG Part 2 section 6.1)*	0.5% of 40g/day = 0.2g/day = 200mg/day
No personal protective factor used	100% contact
Concentration of chloralose in product (4% w/w)	4% of 200mg/day = 8 mg/day
Dermal penetration (based on in vitro test)	3.11%
Operator body weight	60kg
Systemic Exposure	8mg/day X 0.0311/ 60kg = 0.0041 mg/kg bw/day
Clean-up and Disposal	
Systemic Exposure (Assumed to be equal to loading)	0.0041 mg/kg bw/day
Total systemic exposure	= 0.0041 mg/kg bw/day (not foreseen to load and dispose on same day)

Non-professional operator systemic exposure to chloralose was estimated to be 0.0041 mg/kg bw/ day.

Exposure of the general public

There is no study available on the exposure of adults or children in the acute phase including scenarios handling of dead rodents. Indirect exposure was thus estimated based on the scenarios of adult, child and infant handling of dead rodent is described in the TNsG, part 3, appendix 7.2.1. Assumptions and default values used are listed in the table below.

The results of the exposure calculations for the active substance for the general public are laid below.

Dermal exposure due to handling dead rodents	**Adult**	**Child**
Amount of product dislodged to skin	1g	1g
Concentration of Chloralose in product (4% w/w)	4% of 1g = 0.04g = 40 mg	4% of 1g = 0.04g = 40 mg
Dermal adsorption (3.11% based on in vitro test)	3.11% of 40mg = 1.24mg	3.11% of 40mg = 1.24mg
Body weight	60kg	15kg
Systemic exposure	1.24mg /60kg = 0.021 mg/kg bw	1.24mg /15kg = 0.082 mg/kg bw

Infant acute exposure by transient mouthing of poisoning bait treated with repellent is also estimated based on the guidance of the TNsG, part 3, Appendix 7.2.1. and summarized in the table that follows.

Oral exposure due to transient mouthing of bait	Infant
Equivalent of 0.01g of bait is ingested.	0.01g
Concentration of Chloralose in product (4% w/w)	4% of 0.01g = 0.0004g = 0.4 mg
Oral adsorption (assumed 100%)	0.4mg
Body weight	10kg
Systemic exposure	0.4mg /10kg = 0.04 mg/kg bw

Infant mouthing of unsecured bait is also estimated and summarized in the table that follows:

Oral exposure due to transient mouthing of bait	Infant
Equivalent of 5g of bait is ingested.	5g
Concentration of Alphachloralose in product (4% w/w)	4% of 5g = 0.2g = 200 mg
Oral adsorption (assumed 100%)	200 mg
Body weight	10kg
Systemic exposure	200mg /10kg = 20 mg/kg bw

Acute exposure of adults and children handling of dead rodents was estimated to be 0.021 mg/kg bw/day and 0.082 mg/kg bw respectively, while infant acute exposure by transient mouthing of poisoning bait treated with repellent is estimated to be 0.04 mg/kg bw.

Infant mouthing of unsecured bait was estimated to be 20 mg/kg bw. For the sake of harmonization, this scenario was calculated, however due to tamper resistant bait box, the risk of exposure of children and infants is unlikely to occur.

2.7.2.3 Exposure to residues in food

Not applicable. Fast Action Mouse Killer is not intended for use where food for human consumption or feed for livestock is prepared, consumed or stored.

2.7.3 Risk Characterisation

2.7.3.1 Risk for Professional Users

Not applicable. Fast Action Mouse Killer is for non-professional / general public users.

2.7.3.2 Risk for non-professional users and the general public

Risk for non-professional users

Risk characterisation was conducted based on dermal exposures only since inhalation and oral exposures were considered to be negligible. Repeated dose and acute exposure risk were assessed and set out below.

Non-professionals are not expected to use the rodenticide bait on a daily basis nevertheless RMS adopted the conservative approach for risk characterisation calculating the medium term AOEL based on the rat subchronic NOAEL of 15 mg/kg bw/day which was set based on CNS depression effect observed at the next dose level. CMR assessment is not justified and was not conducted.

An Acceptable Operator Exposure Level (AOEL) of 0.15 mg/kg bw/day and a reference MOS (MOSref) of 100 were set based on the NOAEL reffered above and with the assessment factors (AF) of 100 as explained below:

- Conversion LOAEL to NOAEL used an AF of 1 (already using NOAEL),
- Interspecies variation used an AF of 10,
- Intraspecies variation used an AF of 10,
- Route-to-route extrapolation used an AF of 1 (oral absorption is higher than 80%, so oral NOAEL ≈ systemic NOAEL),
- Effect severity used an AF of 1 (reversible effect and substance and metabolites are not bioaccumulative),
- Data gaps/quality used an AF of 1 (study with reliability indicator of 1).

Acute risk characterisation was assessed based on the rat subacute NOAEL of 20 mg/kg bw/day which was set based on the critical effect of CNS depression observed at the next dose level. An acute AOEL of 0.2 mg/kg bw/day and an acute reference MOS of 100 were set based on the NOAEL, with an AF of 100 (as described in the repeat dose above).
Quantitative risk characterization was performed using both the AOEL and MOS approach. The results are summarized in the table below.

Non-professional users – repeated and acute dose exposure risk

Total systemic operator dermal exposure of chloralose per day (mg/kg bw/day)	**AOEL Approach**		**MOS Approach**	
	Repeat exposure	**Acute exposure**	**Repeat exposure**	**Acute exposure**
	% AOEL	% AOEL	MOS	MOS
0.0041mg/kg bw/day	2.7	2.1	3658	4878

Normal use by non-professional of Fast Action Mouse Killer has a high safety margin.

Risk for the general public

Exposure risk for the general public can be summarized as follows:

INDIRECT EXPOSURE AS A RESULT OF USE

As in the assessment above, acute risk characterisation was assessed based on the rat subacute NOAEL of 20 mg/kg bw/day which was set based on the critical effect of CNS depression. An acute AOEL of 0.2 mg/kg bw/day and an acute reference MOS of 100 were set based on the NOAEL, with

an AF of 100 (10 for interspecies variation and 10 for intraspecies variation). The quantitative risk characterisation results for indirect acute exposure of adult and child handling of dead rodents and infant acute exposure by transient mouthing of poisoning bait treated with repellent is summarized below.

Exposure Scenario	Total systemic operator dermal exposure of Chloralose per day (mg/kg bw/day)	AOEL Approach	MOS Approach
		% AOEL	MOS
Adult handling dead mice	0.021 mg/kg bw/day	10.5	952
Child handling dead mice	0.082 mg/kg bw/day	41	244
Infant transient mouthing of bait	0.04 mg/kg bw/day	20	500
Infant mouthing of unsecured bait	20mg/kg bw/day	10000	1

Indirect exposure of adult, child and infant associated with handling dead mice and transient mouthing of bait showed high safety margins indicating negligible risk.

The infant mouthing of unsecured bait has no margin of safety however as the product is only to be used in tamper resistant bait boxes, the risk of exposure is unlikely to occur.

Based on the risk assessment no concern exists for the adverse health effects for general public to chloralose as result of the use of Fast Action Mouse Killer.

2.7.3.3 Risk for consumers via residues

Not applicable.

Fast Action Mouse Killer is not intended for use where food for human consumption or feed for livestock is prepared, consumed or stored.

2.8 Risk assessment for the environment

No new data or information has been submitted since Fast Action Mouse Killer presents a similar composition, as well as the same intended uses, as the representative biocidal product Alphakil Block evaluated during Annex I inclusion.

Considering the similarity in composition and the same type of use, the RMS considers that assessments of the environmental effects and risk to the environment performed for Annex I inclusion regarding product Alphakil Block, based on the active substance, can be used in Fast Action Mouse Killer assessment.

Risks arising from the product were determined based on the assessment of the active substance alone.

Chloralose is not expected to undergo abiotic degradation by hydrolysis (less than 10%).or photolysis in water (194.5 nm).
Chloralose if present in air is expected to be quickly degraded by photo-oxidation ($t_{1/2}$(OH)=3.191h).
Chloralose is not readily (16.67% after 28 days) nor inherent (5% after 28 days) biodegradable.

Chloralose has low adsorption onto soils (K_{aOC} 5.49-120.0).
Chloralose has low bioaccumulation potential both for aquatic (BCF_{fish}=1.05) and terrestrial ($BCF_{earthworm}$=0.92) species.
Regarding the evaluation of hazards for the aquatic environment, chloralose is toxic to fish (96h-LC_{50}=2.4 mg/L) and very toxic to *Daphnia magna* (48h-EC_{50}=0.027 mg/L) and algae (72h-E_bC_{50}= 0.13 mg/L.

Under normal conditions of use, there will be no exposure of chloralose to the terrestrial environment, when it is used in the rodenticide product. There is no mechanism for the chloralose to be released directly into the terrestrial ecosystem because it is only for use indoors in tamper resistant bait boxes. Other routes such as from rodent urine, faeces or carcasses and from disposal of unused bait have been considered and found to be negligible. This means that release to soil of this substance can be considered negligible and the use of chloralose in the rodenticide product will not affect the terrestrial environment.

Only a qualitative environmental risk assessment can be done for the air compartment due to lack of specific effect data. Due to the low vapour pressure (vp=0.00883 Pa) and low Henry's law constant (K_H=5.65 x 10^{-4} Pa. M^3. mol^{-1}) it is not likely that chloralose will be present in the atmosphere at a relevant extent and if present in air it is expected to be quickly degraded by photo-oxidation. Given the negligible level of exposure expected to the atmosphere from the use of chloralose in the rodenticide product there is no risk to the atmospheric compartment.

As chloralose is non biodegradable and hydrolytically stable, and due to its low adsorption onto soils and being readily soluble in water, contamination of surface and groundwater may eventually occur and therefore this emission scenario is considered in the assessment performed.

The route of exposure to the environment being considered is through waste disposal of unspent product in landfill. Given the properties of chloralose (vapour pressure, solubility in water, not degradable, very mobile), and the fact that the formulated product is a solid, the most important route of environmental emission from landfill sites for chloralose would be leaching with water, and as such the two other routes (transport with landfill gas and diffusion to the atmosphere) have not been further considered.

Risk characterization for sewage treatment plant, surface water and groundwater was performed.
The PEC/PNEC ratios for the aquatic environment are all below 1, using worst case scenarios, and therefore the overall risk to the aquatic compartment is considered acceptable. Based on these values it is considered that there is no requirement for further information, testing or risk reduction measures for the aquatic environment in relation to the use of chloralose in the product.

Fast Action Mouse Killer is used indoors and the opportunity for primary poisoning to non-targets is negligible. The product is presented in a tamper-resistant bait box as a non-spill formulation. It is therefore not attractive to granivorous passerine and corvid species so primary poisoning is not an issue.

Chloralose is not likely to bioaccumulate in aquatic or terrestrial species, which leads to a negligible risk of secondary poisoning.

Regarding PBT assessment chloralose can be regarded as potentially persistent (P) or very persistent (vP) in marine environment. Given its low log Kow (log Kow=0.85), it's not considered that chloralose would potentially fulfil the B criterion. The T criterion is fulfilled due to the classification of chloralose as very toxic to aquatic organisms.

Full data on environmental exposure assessment and risk assessment for representative product can be found in Annex 9 to this report.

It can be concluded that no unacceptable risk is expected for any of contemplated environmental compartments regarding the use of Fast Action Mouse Killer.

2.9 Measures to protect man, animals and the environment

Methods and precautions concerning handling and use

Fast Action Mouse Killer bait box is for single use only, ready and easy to use.

Do not use in areas where food for human consumption or feed for livestock is prepared, consumed or stored.

Simply place the Fast Action Mouse Killer bait box where mice have been seen. Ideal locations are against walls, under cupboards or behind furniture (where they cannot be tampered with).

Bait boxes must be placed in areas inaccessible to children, companion animals and non-target animals.

Where possible, secure Fast Action Mouse Killer bait box at its placement site so that it cannot be dragged away by mice and to minimise the risk of consumption and poisoning to children, companion animals and other non-target animals.

When using more than one Fast Action Mouse Killer bait box, place them 3 metres apart.

To maximise the bait take, ensure that alternative food sources have been removed wherever possible.

Fast Action Mouse Killer bait box should only be placed for a maximum of 7-10 days.

Search for and remove dead mice daily during treatment operations to minimise the risk of consumption and poisoning to children, companion animals and other non-target animals.

Dead mice should be double-bagged using plastic bags and either disposed of in a household waste bin with a secure lid to prevent access of wildlife or pets and collected in accordance with local requirements, as appropriate.

Once the mice infestation is controlled do not place further Fast Action Mouse Killer bait box until a new infestation is identified.

In some unusual situations, if mice activity remains, it may be necessary to try another means of control.

Remove all bait boxes after treatment and dispose of in accordance with local requirements. Bait boxes must not be reused or recycled.

Wash hands after use of the product, and before eating, drinking or smoking.

If swallowed, seek medical advice immediately and show the container or label.

Methods and precautions concerning storage

Keep only in the original container.

Store in a cool, dry, well-ventilated place

Avoid extremes of temperature (e.g. below 0°C and above 40°C).

Keep out of the reach of children and companion animals.

Keep away from food, drink and animal feedingstuffs.

Methods and precautions concerning transport

Not classified as hazardous for transport, under International Road or Maritime Transport Regulations (ADR 2013, IMDG 2012).

Methods and precautions concerning fire

In case of fire use foam, water-fog, carbon dioxide or dry powder extinguishers.

Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available

Ingestion of the product in large quantities may lead to nausea, vomiting, nervous system depression, headache and weakness leading to unconsciousness.

General advice:

In the event of accidental consumption the patient should be kept quiet and warm and a doctor called. Airways should be kept clear. Avoid sedatives. If cats or dogs are affected, similar first aid treatment should be employed.
For further information, contact the National Poison Information Centre. In Portugal (CIAV) - tel: 808 250 143 or contact 112. Retain the label for reference.

ADVICE FOR DOCTORS:

Treatment is symptomatic and there is no specific antidote.

First Aid Advice:

Inhalation: Unlikely route of exposure. However, remove patient to fresh air, keep warm and at rest. Apply supportive measures if necessary and seek medical attention.

Eye contact: Rinse affected eye with clean running water, or eyewash solution for at least 15 minutes holding eyelids well apart. Rinse entire surface and do not allow run-off to contaminate unaffected eye. Seek medical attention.

Skin contact: Remove and wash contaminated clothing immediately. Wash affected area thoroughly with soap and water. If the patient feels unwell, seek medical advice.

Ingestion: Do NOT induce vomiting. If unconscious place in the recovery position and apply supportive measures if necessary. If conscious give patient up to ½ litre or 1 pint of water to drink. Seek medical attention (show the label where possible).

Emergency measures to protect the environment

Avoid release to the environment.
Keep away from drains, surface and ground water, and soil.
DO NOT contaminate watercourses or ground.

Procedures, if any, for cleaning application equipment

Not applicable.

Identity of relevant combustion products in cases of fire

Chlorine and other toxic gases may be formed in the event of a fire.

Procedures for waste management of the biocidal product and its packaging and where relevant, treated waste material for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration

Dispose of bait boxes in accordance with local requirements. Bait boxes must not be reused or recycled.

Possibility of destruction or decontamination following accidental release

Collect up spilt bait blocks (wear suitable gloves), if intact they can be reused, otherwise transfer to a suitable container for subsequent disposal.

Keep away from drains, surface and ground water, and soil.

Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms

Measures to minimize the risk of secondary poisoning of wildlife will be taken. The product is a tamper resistant bait box containing the chloralose bait intended for indoor use only. Collection of bait boxes after termination of the treatment and collection of dead mice during the treatment also minimize potential adverse effects on non-target organisms.

Aquatic toxicity

Very toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment.

Repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms

Fast Action Mouse Killer contains 100 ppm Bitrex (Denatonium benzoate) as a taste aversive agent to help prevent ingestion of significant amounts of the bait by humans –particularly children.

3 Proposal for decision

The evaluation presented has shown that sufficient data have been provided to verify the outcome and conclusions, and permits the authorisation, for use as a rodenticide (PT 14) for the control of house mice (*mus musculus domesticus*), of the ready-to-use product Fast Action Mouse Killer, containing the active substance chloralose at 4% w/w for non-professional / general public users.

Chloralose is an active substance considered as a candidate for substitution in accordance with article 10(1) of BPR. At renewal of this authorisation, a comparative assessment should be included.

Conditions of authorisation

Type of product: PT 14 - rodenticides

Intended Use: rodenticide for control of house mouse (*Mus musculus domesticus*) only, for non-professional / general public
Active substance: Chloralose 4% w/w
Purity of active substance: minimum 825 g/kg
Formulation of biocidal product: Ready to use two solid bait blocks in a tamper resistance bait box
The product shall contain an aversive agent
The product shall contain a dye
Place of treatment: indoor use only
Shelf life of product: 2 years

4 Annexes

4.1 Annex 1: Summary of product characteristics

See separated document.

4.2 Annex 2: List of studies reviewed

List of <u>new data</u>[2] submitted in support of the evaluation of the active substance

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
Section A3 – Physical and Chemical Properties	A3.11	Daniel Baker	2008	Relative self-ignition temperature determination on Chloralose Chilworth Technology Limited, Southampton, UK Report n.º GLP301107R1V1/08 GLP - yes	Physalys sarl.	☒	☐	☒	☐
Add rows as necessary									

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

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
Section B3 – Physical and Chemical Properties	B3.7a	S. Keay	2012	Storage Stability: Alpha Rapid Rentokil European Technical Centre Study 244/72 (Applicant reference number ALPHCHL-373)	Physalys sarl.	☒	☐	☒	☐

2 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	
Section B3 – Physical and Chemical Properties	B3.7b	S. Keay	2012	Storage Stability: Fast Action Mouse Killer Rentokil European Technical Centre Study 244/73 (Applicant reference number ALPHCHL-374)	Physalys sarl.	☒	☐	☒	☐
Section B3 – Physical and Chemical Properties	B3.7c	S. Keay	2012	Storage Stability: Alphachloralo-se Technical Rentokil European Technical Centre Study 244/78 (Applicant reference number ALPHCHL-375)	Physalys sarl.	☒	☐	☒	☐
Section B3 – Physical and Chemical Properties	B3.7d	Dr. A. J. Brigham	2006	Accelerated Shelf Life: Fast Action Mouse Killer Rentokil Pest Control Technical Committee Report 06/04 Project 298/24	Physalys sarl.	☒	☐	☒	☐
Section B5 – Intended uses and efficacy	B5.10.10	Dr. A. J. Brigham	2004	Rodenticide efficacy field trial: Alphachloralose Bait Blocks (4% alphachloralose) against mice at Orchard Nursery Pest Control Technical Committee Report 05/02 Project No.248/11 / GLP / Unpublished (Applicant's reference number ALPHCHL-305)	Physalys sarl.	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
Section B5 – Intended uses and efficacy	B5.10.11	Dr. A. J. Brigham	2004	Rodenticide Efficacy Field Trial: Alphchloralose Bait Blocks (4% alphachloralose) against Mice at Deers Leap Park Pest Control Technical Committee Report 05/01 Project No.248/9 / GLP / Unpublished (Applicant's reference number ALPHCHL 306)	Physalys sarl.	☒	☐	☒	☐
Section B5 – Intended uses and efficacy	B5.10.12	Dr. A. J. Brigham	2005	Rodenticide Efficacy Field Trial: Alphchloralose Bait Blocks (4%alphachloralose) against Mice at Heatherdene Farm Pest Control Technical Committee Report 05/07 Project No.248/15 / GLP / Unpublished (Applicant's reference number ALPHCHL 315)	Physalys sarl.	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
Section B5 – Intended uses and efficacy	B5.10.13	Dr. A. J. Brigham	2005	Rodenticide efficacy simulated field trial with acclimatisation: Alphachloralose Bait Blocks (4% alphachloralose) against captive bred house mice within pens at Rentokil Initial Research and Development, Felcourt, east Grinstead, RH19 2JY. Pest Control technical Committee Report 05/09, project 248/23, GLP / Unpublished (Applicant's reference number ALPHCHL 320)	Physalys sarl.	☒	☐	☒	☐
Section B5 – Intended uses and efficacy	B5.10.14	Dr. A. J. Brigham	2005	Rodenticide efficacy simulated field trial: Alphachloralose Bait Blocks (4% alphachloralose) against captive bred house mice within pens at Rentokil Initial Research and Development, Felcourt, East Grinstead, RH19 2JY. Technical Committee Report 05/08. Project 248/22. Applicant reference number ALPHCHL-321	Physalys sarl.	☒	☐	☒	☐
Add rows as necessary									

4.3 Annex 3: Analytical methods residues – active substance

Chloralose

Methods suitable for the determination of residues (monitoring methods)

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Doc IIIA_A4.3-3	Cucumber	0.01 mg/kg	GC-ECD GC-MS	None	CEFIC EBPF Rodenticides Data Development Group
	Wheat	No LOQ validated	GC-ECD (Column 1) GC-ECD (Column 2)	monitoring and control purposes	
	oil-seed rape	No LOQ validated	GC-ECD GC-MS	monitoring and control purposes	
	lemon	No LOQ validated	GC-ECD GC-MS	monitoring and control purposes	

Methods for foodstuffs of animal origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Doc IIIA_A4.3-3	Meat (muscle)	No LOQ validated	GC-ECD GC-MS	monitoring and control purposes	CEFIC EBPF Rodenticides Data Development Group

Methods for soil

reference	LOQ (mg/kg)	principle	comment	owner
Doc IIIA_A4.2a-3 Doc IIIA_A4.2a-4	0.05 mg/kg	GC-MS	None	Physalys

Methods for drinking water and surface water

reference	matrix	LOQ (µg/l)	principle	comment	owner
Doc IIIA_A4.2c-2	Water	0.1 µg/L	LC/MS/MS	None	Physalys

Methods for air

reference	LOQ (µg/m3)	principle	comment	owner
-	-	-	not required, since the biocidal product is formulated into a non-volatile solid	-

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner
-	-	-	-	not required, since chloralose is not classified as toxic or very toxic	-

4.4 Annex 4: Toxicology and metabolism – active substance

Chloralose

Threshold Limits and other Values for Human Health Risk Assessment

Summary			
	Value	Study	AF
AOEL long-term	0.15 mg/kg bw/day	Subchronic oral toxicity test Rat	100
AOEL medium-term	0.15 mg/kg bw/day	Subchronic oral toxicity test Rat 90 days	100
AOEL acute	0.2 mg/kg bw/day	Repeated dose toxicity (oral) Rat 28 days	100

Inhalative absorption	-
Oral absorption	>80%
Dermal absorption	3.11% per day (based on in vitro test on product as a worst-case scenario)

Classification	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Xn; R20/22 Harmful by inhalation and if swallowed
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute Tox. 4 *H332 Acute Tox. 4 * H302

4.5 Annex 5: Toxicology – biocidal product

Fast Action Mouse Killer

General information

Formulation Type	Ready to use Solid Bait Block in TRBB
Active substance(s) (incl. content)	Chloralose 4%
Category	PT 14 (Rodenticides)

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	Justification for non-submission of data provided and accepted
Rat LD50 dermal (OECD 402)	Justification for non-submission of data provided and accepted
Rat LC50 inhalation (OECD 403)	Justification for non-submission of data provided and accepted
Skin irritation (OECD 404)	Justification for non-submission of data provided and accepted
Eye irritation (OECD 405)	Justification for non-submission of data provided and accepted
Skin sensitisation (OECD 429; LLNA)	Justification for non-submission of data provided and accepted

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	
Toxicological data on active substance(s) (not tested with the preparation)	Fast Action Mouse Killer is not intended for use where food for human consumption or feed for livestock is prepared, consumed or stored. If Fast Action Mouse Killer was to be used in an area where food is prepared, consumed or stored e.g. in a food factory, it would be in such a way that there would be no contamination of the food or feeding stuffs (e.g. tamper-resistant boxes). The use pattern of Fast Action Mouse Killer, therefore make it unnecessary to submit data on feeding and metabolism studies in livestock.
Toxicological data on non-active substance(s) (not tested with the preparation)	No ingredients included in the formulated product, are considered to be of toxicological concern in view of their toxicity profile and concentration in the product.
Further toxicological information	

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	N: Dangerous for the environment R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment S1 - Keep out of the reach of children S13 - Keep away from food, drink and animal feedingstuffs. S20/21 - When using do not eat, drink or smoke. S35 - This material and its container must be disposed of in a safe way. S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S61 – Avoid release to the environment. Refer to special instructions / safety data sheet.
Regulation 1272/2008/EC	Acute Aquatic Category 1 Chronic Aquatic Category 1 H410: Very toxic to aquatic life with long lasting effects P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read label before use. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P501: Dispose of contents/container to accordance with local requirements.

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

Fast Action Mouse Killer

General information	
Formulation Type	Ready to use Solid Bait Block in TRBB
Active substance(s) (incl. content)	Chloralose 4%
Category	PT 14 (Rodenticides)
Authorisation number	

Chloralose

Data base for exposure estimation	
according to Chambers & Snowdon	Appendix: Toxicology and metabolism – active substance/AR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Non-professional operator systemic exposure	0.0041 mg/kg bw/day
Secondary exposure, acute (Adult handling dead mice)	0.021 mg/kg bw/day
Secondary exposure, acute (Child handling dead mice)	0.082 mg/kg bw/day
Secondary exposure, acute (Infant transient mouthing of bait)	0.04 mg/kg bw/day
Secondary exposure, acute (Infant mouthing of unsecured bait)	20mg/kg bw/day

Conclusion:

Normal use by non-professional of Fast Action Mouse Killer has a high safety margin.

Indirect exposure of adult, child and infant associated with handling dead mice and transient mouthing of bait showed high safety margins indicating negligible risk.

The infant mouthing of unsecured bait has no margin of safety however as the product is only to be used in tamper resistant bait boxes, the risk of exposure is unlikely to occur.

Exposure of the general public to the biocidal product containing chloralose as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

4.8 Annex 8: Residue behaviour

Fast Action Mouse Killer

Intended Use (critical application): non-professional / general public use
Active substance(s): Chloralose
Formulation of biocidal product: Ready to use two solid bait blocks in tamper resistant bait box
Place of treatment: indoor use only
House mouse (*Mus musculus domesticus*): The product is for single use, ready and easy to use. Simply place the box where mice have been seen. Ideal locations are against walls, under cupboards or behind furniture (where they cannot be tampered with). When using both boxes, place them a few metres apart. Not for use in areas where food for human consumption or feed for livestock is prepared, consumed or stored. Bait boxes should only be placed for a maximum of 7-10 days.
Remove all bait boxes after treatment and dispose of in accordance with local requirements. Once the mice population is controlled, do not place further bait box until a new infestation is identified. In some unusual situations, if mouse activity remains, it may be necessary to try another means of control of bait.

The intended use descriptions of the chloralose-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed.

4.9 Annex 9: Risk assessment for the environment

1 ENVIRONMENTAL EFFECTS ASSESSMENT

1.1 FATE AND DISTRIBUTION IN THE ENVIRONMENT

1.1.1 DEGRADATION

1.1.1.1 BIODEGRADATION

The biodegradation behaviour of chloralose was studied in laboratory conditions. Ready biodegradation study revealed that the substance was not readily biodegradable (16.67% after 28 days). The reference substance exhibited a normal pattern of degradation (up to 94.04% within 28 days).

Another study was performed to investigate the inherent biodegradability of chloralose.
The test material attained 19% degradation after 28 days. The results obtained from the abiotic test vessel showed 14% loss of DOC occurred over the study period. Correction of the DOC degradation rate for abiotic loss showed that the test material achieved 5% biodegradation after 28 days.
Chloralose is not readily nor inherent biodegradable.

1.1.1.2 ABIOTIC DEGRADATION

HYDROLYSIS

Abiotic degradation of chloralose, by hydrolysis, was studied according to OECD test guideline 111, at three different pH values (4, 5 and 9). Only the preliminary test was performed by incubating a solution of the active substance in buffered solutions, in the dark, at 50°C for 5 days, as the observed final degradation was less than 10%.
The results indicate that chloralose is hydrolytically stable and the half-life can be expected to exceed one year at 25ºC.

PHOTOLYSIS IN WATER

Chloralose has a UV absorption maxima out of the range of 290-800nm so is not expected to undergo abiotic degradation by photolysis in water.

PHOTOTRANSFORMATION IN AIR

The photo-oxidative degradation of chloralose in air was estimated by a structural activity relationship (QSAR) method using the Atmospheric Oxidation Program v1.91 (AOPWIN). The half-life in air for the OH radicals is estimated to be $t_{1/2}$ (OH) - 3.191 h ($1.5*10^6$ OH radicals/cm^3).
Due to the low vapour pressure and low Henry's law constant it is not likely that chloralose will be present in the atmosphere at a relevant extent and if present in air it is expected to be quickly degraded by photo-oxidation.

1.1.1.3 DISTRIBUTION

ADSORPTION ONTO/DESORPTION FROM SOILS

Adsorption of chloralose onto soils has been studied in five soils at 1:1 soil-solution ratio, using the batch equilibrium method.
Chloralose is slightly adsorbed onto soil. The amount of chloralose adsorbed to soil at equilibrium time (32 h) ranged from 21.43% (Motivahiyal loamy sand) to 31.78% (Vansda clay loam/clay).
Based on KaOC values, which ranged from 5.49 (Jageshwar sand/loamy sand) to 120.00 (Vansda clay loam/clay) and according to SSLRC mobility classification (Soil Survey and Land Research Council, UK), chloralose can be considered very mobile in sand/ loamy sand soil, mobile in sandy clay loam, clay and loamy sand soils and moderately mobile in clay loam/ clay soil.
Due to its low adsorption onto soils and being readily soluble in water, chloralose is expected to move from soil into water.

WATER/SOIL-AIR

The low vapour pressure and low Henry's law constant of chloralose, indicates that it is non volatile and it is not expected to move from water and soil to air. If present in the air it is expected to be quickly degraded by photo-oxidation.

1.1.2 ACCUMULATION

Measurements of aquatic bioconcentration of chloralose were not performed due to its physical and chemical properties and its limited exposure to the aquatic environment. According to the Technical Guidance Document on Risk Assessment (European Communities, 2003), there is an indication of bioaccumulation potential if the substance has a log Kow ≥ 3 or is highly adsorptive or belongs to a class of substances known to have a potential to accumulate in living organisms or there are indications from structural features and there is no mitigating property such as hydrolysis. Chloralose has log Kow of 0.85 and is not highly adsorptive nor are there any other indications that it has the potential to bioaccumulate. It is on this basis that no further investigation about the bioaccumulation potential of chloralose has been conducted.

Even so, if a linear relationship included on the above mentioned document was to be applied in the present case, in spite of the fact that log Kow is below the stated range of application (2 – 6), the result would be:

$\log BCFfish = 0.85 \bullet \log Kow - 0.70 = 0.023$,

$BCFfish = 1.05$,

which confirms the low bioaccumulation potential of chloralose in aquatic species.
Regarding terrestrial bioconcentration, no estimations were performed since the indicated use of chloralose does not indicate a concern for the terrestrial compartment. Nevertheless, on applying the equation given on the TGD on Risk Assessment (2003), the following result is obtained:

$BCFearthworm = 0.84 + 0.012 \bullet Kow = 0.92$,

which confirms the low bioaccumulation potential of chloralose in terrestrial species.
Additional note has to be given to the surface tension of chloralose, 50.1 mN/m, which lies slightly above the trigger value of ≤50 mN/m.
Chloralose has low bioaccumulation potential both for aquatic and terrestrial species.

Overall Conclusions:
Chloralose is not expected to undergo abiotic degradation by hydrolysis or photolysis in water.
Chloralose if present in air it is expected to be quickly degraded by photo-oxidation.
Chloralose is not readily nor inherent biodegradable.
Due to its low adsorption onto soils and being readily soluble in water, chloralose is expected to move from soil into water.
Chloralose is intended to be indoor use only, and taken into account mice behaviour, release to soil of this substance can be considered negligible.
Nevertheless, as it is non biodegradable and hydrolytically stable, and due to its low adsorption onto soils, contamination of surface and groundwater may eventually occur and therefore this emission scenario is considered in the assessment performed.
Chloralose has low bioaccumulation potential both for aquatic and terrestrial species.

1.2 EFFECT ON ENVIRONMENTAL ORGANISMS

1.2.1 AQUATIC COMPARTMENT

Acute toxicity to fish

Two studies performed to assess the acute toxicity (96h) LC_{50} of chloralose in rainbow trout, *Oncorhynchus mykiss*, were submitted. The methods followed were per guideline EC C.1 (1992).

In study 1 the 96h EC0 was found to be 0.6 mg/L. The 96h LC50 of chloralose was determined as 2.40 mg/L, with 95% fiducial limits between 1.61 and 3.57 mg/L.
In study 2 the 96h EC0 was found to be 0.78 mg/L. The 96h LC50 of chloralose was determined as 5.01 mg/L, with 95% fiducial limits between 2.68 and 9.38 mg/L.
Based on these results chloralose is toxic to fish.

Acute toxicity to invertebrates

Two studies performed to assess the acute immobilisation, 24 and 48h EC50, caused by chloralose in *Daphnia magna* were submitted. The methods followed were per guideline EC C.2 (1992).
In study 1 the 48h EC0 of chloralose was found to be 0.006 mg/L. The 48h EC50 of chloralose was determined as 0.027 mg/L with 95% fiducial limits of 0.020 and 0.036 mg/L.
In study 2 the 48h EC0 was found to be 0.06 mg/L. The 48h EC50 of chloralose was determined as 0.36 mg/L with 95% fiducial limits of 0.20 and 0.64 mg/L.
Based on these results chloralose is very toxic to *Daphnia magna*.

Growth inhibition on algae

Two studies performed to assess the alga *Pseudokirchneriella subcapitata* (formerly known as *Selenastrum capricornutum*) growth inhibition caused by chloralose were submitted. The methods followed were per guideline EC C.3 (1992).
In study 1 the EC50 (0 – 72h) value for chloralose was determined as 0.13 mg/L, with 95% fiducial limits between 0.07 and 0.25 mg/L, and 0.52 mg/L, with 95% fiducial limits between 0.18 and 1.46 mg/L, for growth inhibition (EbC50) and growth rate reduction (ErC50), respectively. At 0.02 mg/L concentration there was no statistically growth rate reduction at 5% level when compared with the control values. Hence the NOEC was found to be 0.02 mg/L.
In study 2 the EC50 (0 – 72h) value for chloralose was determined as 1.00 mg/L, with 95% fiducial limits between 0.85 and 1.17 mg/L, and 4.90 mg/L, with 95% fiducial limits between 3.66 and 6.55 mg/L, for growth inhibition (EbC50) and growth rate reduction (ErC50), respectively. The growth rate reduction was taken into consideration to decide the NOEC and LOEC. The NOEC and LOEC of chloralose over the entire 72 h exposure period were found to be 0.13 and 0.28 mg/L, respectively.
Based on these results chloralose is very toxic to algae.

1.2.2 ATMOSPHERE

No studies were submitted since chloralose is non volatile (vapour pressure = 0.00883 Pa) nor occurrence in air is otherwise likely. It is not sprayed, it is formulated into a non volatile solid and there is no reason to think occurrence in air is possible.

1.2.3 TERRESTRIAL COMPARTMENT

No studies were submitted since the indicated use of chloralose does not evidence a concern for the terrestrial flora and fauna nor a long term exposure. This is because:

1. Chloralose-containing biocides are intended for indoor use only. Environmental exposures are greatly reduced by the fact it will not be used outdoors. It is acknowledged that the indoor use only restriction does not eliminate environmental exposure completely e.g. from rodent urine, faeces and carcasses of animals that have taken the bait and moved outdoors, however the metabolism of chloralose is fast and immobilisation of animals occurs shortly after bait consumption.

2. Chloralose-containing biocides are not intended for direct application to the environment e.g. by spraying, or placement directly onto the ground or soil. Chloralose containing biocides are used in tamper resistant bait boxes (or similar). The use of closed bait stations (such as the tamper resistant bait box) not only minimises the risk of release directly to the environment, but it also reduces the potential for primary poisoning of non-target species including cats, dogs and children.

1.2.4 NON COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN (SECONDARY POISONING)

There is unlikely to be an issue of secondary poisoning since a limited exposure to the environment is expected. Chloralose is for indoor use only and immobilisation of mice occurs shortly after bait consumption.
Due to its rapid narcotic effect mice do not eat large portions of the poison bait. Mammalian predators may catch a poisoned mouse but guidance advises that with LD50 values higher than 100 mg/kg for cats and dogs a secondary risk is considered negligible. (Emission Scenario Document For Biocides Used As Rodenticides. J Larsen, Danish EPA, March 2003). This is the case for chloralose given that the LD50 for cats is 100-250 mg/kg and dogs 600 mg/kg.
Additionally, accumulation of chloralose through the food chains is not likely to occur given its low log Kow (0.85 ± 0.03).
Given the above, no further assessment on secondary poisoning is considered necessary.

1.3. DETERMINATION OF PNECS

1.3.1 PNECaquatic

The base set of acute aquatic data is used to assess the PNEC aquatic for the active substance chloralose. Studies for each of three trophic levels of the base set (fish, Daphnia and algae) resulted in the following:

	Study 1	Study 2
Fish (*Oncorhynchus mykiss*) 96h LC50	2.4 mg/L	5.01 mg/L
Daphnia magna 48h EC50	0.027 mg/L	0.36 mg/L
Algae (*Pseudokirchneriella subcapitata*) 72h EC50	0.52mg/L	4.90 mg/L

The above shows that the most sensitive species of those tested is *Daphnia magna*. This 48h EC50 figure is used in conjunction with an assessment factor to give the PNEC. Because the risk assessment needs to cover all species and life stages, a conservative and protective factor of 1000 is normally used when there is short term data from three trophic levels. Additionally, TGD on Risk Assessment (2003) states that if more than one L(E)C50 value is available for the same species and end-point, the geometric mean must be used. Hence:

$$Geometric\ mean = \sqrt{0.027 \times 0.36} = 0.099\ mg/L$$

$$PNEC_{aquatic} = \frac{0.099\ mg/L}{1000} = 0.099\ \mu g/L$$

1.3.2 PNECmicroorganisms

The predicted no effect concentration for microorganisms can be derived from data obtained on a respiration inhibition test conducted in accordance with EC method C.11. TGD on Risk Assessment (2003) recommends that if an EC10 from a respiration inhibition test is used an assessment factor of 10 should be applied. Hence:

$$PNEC_{microorganisms} = \frac{702.89\ mg/L}{10} = 70.29\ mg/L$$

1.3.3 PNECsediment

To avoid extensive testing, TGD on Risk Assessment (2003) advises that a log Kow of ≥ 3 can be used as a trigger value for sediment effects assessment. The log Kow for chloralose is 0.85 ± 0.03, therefore there is no requirement to carry out this assessment.

1.3.4 PNECsoil

Not relevant (please refer to 1.2.3)

1.3.5 PNECair

Not relevant (please refer to1.2.2)

2 ENVIRONMENTAL EXPOSURE ASSESSMENT

Fast Action Mouse Killer is designed for indoor use only. Environmental exposures are greatly reduced by the fact that it cannot be used outdoors. Environmental exposure may possibly occur through urine, faeces and carcasses of animals that have taken the bait and moved outdoors, however metabolism of chloralose is quick and immobilisation of animals occurs shortly after bait consumption minimising this route of exposure. The product is a non volatile solid, the vapour pressure of chloralose is 8.83 x 10^{-3} Pa thus evaporation will be so small that exposure to the air is negligible.
Potential exposure during product manufacture is negligible.
The route of exposure to the environment being considered is through waste disposal of unspent product. Given the properties of chloralose (vapour pressure, solubility in water, not degradable, very mobile), and the fact that the formulated product is a solid, the most important route of environmental emission from landfill sites for chloralose would be leaching with water, and as such the two other routes (transport with landfill gas and diffusion to the atmosphere) have not been considered further. With respect to the leachate produced, the leachate is collected and treated before being discharged or returned to the landfill site, according to the Landfill Directive (99/31/EC), which came into force 26 April, 1999, with a final date for implementation in the Member States of 16.07.2001. The Directive's overall aim is 'to prevent or reduce as far as possible negative effects on the environment, in particular […] the pollution of surface water, groundwater, soil and air' and contains provisions for aspects such as water control and leachate management and protection of soil and water. According to the Directive, appropriate measures have to be taken, with respect to the characteristics of the landfill and the meteorological conditions, in order to collect contaminated water and leachate (if an assessment based on consideration of the location of the landfill and the waste to be accepted shows that the landfill poses no potential hazard to the environment, the competent authority may decide that this provision does not apply) and to treat contaminated water and leachate collected from the landfill to the appropriate standard required for their discharge.
Leachate produced from the landfill is therefore collected and treated before being either discharged or re-cycled.
Leachate characteristics depend upon several factors including: waste composition; age of waste; degree of compaction; decomposition phase; waste filling procedures; waste moisture content; rate of water movement; and temperature (Armstrong and Rowe, 1999). There are three general phases of waste decomposition. The first aerobic phase (immediately after waste placement) is dominated by aerobic degradation. Following this, when oxygen has been depleted, anaerobic degradation dominates the decomposition process. This phase is characterised by high biochemical and chemical oxygen demand (BOD and COD) and a typical pH of 5 – 6. The third phase of decomposition occurs when anaerobic methanogenic bacteria become dominant. The pH is increased to between pH 7 and 8 and the BOD/COD ratio is reduced.

The most significant potential exposure pathway for chloralose is considered to be disposal to landfill, and then via leachate, to the sewage treatment plant and, subsequently, to the aquatic environment. In accordance with the TGD, it is assumed that 100% chloralose waste will be disposed of in the landfill.

2.1 FATE AND DISTRIBUTION IN THE ENVIRONMENT

Apart from the active substance chloralose, there is only one component of the product Fast Action Mouse Killer which is classified as dangerous for the environment. This is the taste aversant. Because it is at such a low level the hazard does not carry through to the product. Consequently only the information provided for the active substance is relevant for the product as the co-formulants of Fast Action Mouse Killer do not alter the environmental fate or distribution.

2.2 PEC IN SEWAGE TREATMENT PLANT, SURFACE WATER, GROUNDWATER AND SEDIMENT

The model of a sanitary landfill included on RIVM report 601450009 – Emission scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC) – was followed in order to calculate for a certain year the maximum quantities of chloralose loads to percolating water, from the first year after the start of utilisation of the landfill up to 5 years after closure.

Table 1 – Sanitary landfill model (Input data)

Variable/parameter (unit)	**Symbol**	**Value**[1]
Bottom surface of the landfill (m^2)	AREAlandf	300,000
Total height of waste dumped (m)	DEPTHwaste	20
Density of the waste ($kg.m^{-3}$)	RHOwaste	1000
Utilisation period (yr)	Tutil	15
Wet precipitation ($m.yr^{-1}$)	RAINRATE	0.8
Precipitation surplus in sector with		
- surface without vegetation ($m.yr^{-1}$)	WSbare	0.45
- surface with vegetation ($m.yr^{-1}$)	WSveg	0.3
- surface with top seal ($m.yr^{-1}$)	WSfinal	0.05
Water produced in waste sector ($m3.yr^{-1}$)	Vwaterproduced	0
Rate constant for degradation in bulk soil (d^{-1})	kdegsoil	0[2]
Soil-water partition coefficient ($m3.m^{-3}$)	Ksoil-water	1.05[3]
Fraction of substance leached and penetrating into the subsoil (-)	Fleachsubsoil	0.05

1 – default values except where noted.

2 – as a worst case scenario and taking into account degradation studies.

3 – corresponds to a Ksoil-water of 0.62 cm3/g taken from adsorption/desorption studies (considering a bulk density of wet soil of 1.7 g/cm3). This value was determined for Jageswar soil which presented the lowest Koc, thus the highest mobility.

Table 2 – Sanitary landfill model (Intermediate calculations)

Parameter (unit)	**Symbol**	**Value**
Total volume of the landfill (m^3)	Vlandf	4460280
Mass of the waste dumped annually ($tonnes.yr^{-1}$)	Qwastelandf	297352
Amount of percolating water in section where dumping takes place in current year ($m3.yr^{-1}$)	Vwaterdump	9000

Amount of percolating water in a section where dumping has taken place in one of the previous years during the utilisation period ($m3.yr^{-1}$)	Vwaterveg	6000
Amount of percolating water in a section where dumping has taken place after closure of the landfill and application of final seal ($m3.yr^{-1}$)	Vwaterfinal	1000
Amount of water in section where dumping still has to take place in future year ($m3.yr^{-1}$)	Vwateropen	16000
Rate constant for degradation of substance in waste (d^{-1})	kdegwaste_subst	0
Rate constant for leaching of substance in sector with a surface without vegetation (yr^{-1})	kleachbare	0.021
Rate constant for leaching of substance in sector with a surface with vegetation (yr^{-1})	kleachveg	0.014
Rate constant for leaching of substance in sector with a surface with top seal (yr^{-1})	kleachfinal	0.0024
Overall removal rate constant in sector with surface without vegetation (yr^{-1})	krembare	0.021
Overall removal rate constant in sector with surface with vegetation (yr^{-1})	kremveg	0.014
Overall removal rate constant in sector with surface with top seal (yr^{-1})	kremfinal	0.0024

- Calculation of Csubst_landf0

The initial concentration of substance in landfilled waste can be calculated through the following equation:

$$Csubst\_landf_0 = \frac{Qsubst\_prod}{Qwaste\_reg}$$

where Qsubst_prod – quantity of biocide for application in product in total waste ($kg.yr^{-1}$)
Qwaste_reg – total quantity of waste in the region disposed in landfill ($ktonnes.yr^{-1}$)

No substantive data exists for the total amounts of rodenticidal active substances sold within the EU at this time.

The TGD on Environmental Risk Assessment gives no quantitative data on waste disposal operations in the EU, however states that 'if a major share of a substance placed on the market remains in chemical products or articles at the end of their service life (releases during production, processing and use are relatively small), the waste life-cycle stage of the substance may need particular attention'. Therefore, only a proportion of the total amount marketed (i.e. the unspent product) is expected to be disposed of via landfill.

Rodents generally die in their harbourages but occasionally "in the open", - mostly indoors but occasionally at the buildings curtilage. If they die in their harbourages, their bodies will contain a proportion of the parent compound derived from the rodenticide together with the metabolites arising from its degradation. These scenarios will be considered later.

If rodents die "in the open", i.e. visible, but still indoors, current regulatory advice is to collect the bodies and send them for disposal as controlled waste. If as a worst case, all the rodent bodies arising from the use of chloralose were available and able to be collected, and they contained all of the ingested parent compound, then we have considered Qsubst_prod to be 600 $kg.yr^{-1}$.

We have used available data for the waste generated each year in the UK.

Table 3 – Waste disposal in the UK

Type of waste	**Volumes of waste generated each year in the UK (based on figures gathered in 2000/2001)***	**Volumes disposed of at landfill***
Total (all waste, including controlled waste, municipal waste, commercial and industrial waste etc.)	375 million tonnes	--
Municipal waste	28.2 million tonnes (of which 25.1 million tonnes is from household waste).	78%
Industry waste	47 million tonnes	44%
Commercial business waste	24 million tonnes	68%
Construction/demolition waste	89 million tonnes	--
Materials such as agricultural waste, mining and quarry waste, sewage sludge etc.	Balance (> 150 million tonnes)	--

*Figures are from: Anon (2003) Waste not, Want not - A Strategy for Tackling the Waste Problem in England. From: www.number-10.gov.uk/su/waste/report/02.html

Considering, as a worst case, that chloralose is sent for landfill included on municipal waste, without any treatment:

$$Qwaste\_reg = 0.78 \times 28.2 \times 10^3 = 22{,}000\ ktonnes.yr^{-1}$$

Thus:
$$Csubst\_landf0 = \frac{600}{22000} = 0.027\ mg.kg^{-1}$$

The following tables include the determination of several parameters through the landfill life-cycle.

Table 4 - Amount of percolating water (Vwater_percol) for year $i = 1 \ldots Tutil+5$ in the entire landfill ($m^3.yr^{-1}$)

Year (*i*)	Vwater_percoli
1	233000
2	223000
3	213000
4	203000
5	193000
6	183000
7	173000
8	163000
9	153000
10	143000
11	133000
12	123000
13	113000

14	103000
15	93000
16	15000
17	15000
18	15000
19	15000
20	15000

Table 5–Concentration in waste (Csubst_landf) at beginning of year *i* in a sector for *i* = 1…Tutil+5 ($mg.kg^{-1}$)

Year (*i*)	Csubst_landfi
1	2.67E-02
2	2.59E-02
3	2.49E-02
4	2.35E-02
5	2.19E-02
6	2.01E-02
7	1.82E-02
8	1.62E-02
9	1.43E-02
10	1.24E-02
11	1.06E-02
12	8.92E-03
13	7.42E-03
14	6.08E-03
15	4.91E-03
16	4.73E-03
17	4.54E-03
18	4.35E-03
19	4.16E-03
20	3.97E-03

Table 6 – Amount removed from waste (Qrem_sec) in a sector in year *i* for *i* = 1…Tutil+5 ($kg.yr^{-1}$)

Year (*i*)	Qrem_seci
1	1.71E-04
2	2.23E-04
3	3.22E-04
4	4.09E-04
5	4.80E-04
6	5.32E-04
7	5.66E-04
8	5.82E-04

9	5.80E-04
10	5.63E-04
11	5.33E-04
12	4.94E-04
13	4.48E-04
14	3.98E-04
15	3.47E-04
16	5.44E-05
17	5.55E-05
18	5.64E-05
19	5.70E-05
20	5.73E-05

Table 7 – Amount of substance leached (Qleach_sec) in a sector in year *i* for *i* = 1 Tutil+5 ($kg.yr^{-1}$)

Year (*i*)	Qleach_seci
1	1.71E-04
2	2.23E-04
3	3.22E-04
4	4.09E-04
5	4.80E-04
6	5.32E-04
7	5.66E-04
8	5.82E-04
9	5.80E-04
10	5.63E-04
11	5.33E-04
12	4.94E-04
13	4.48E-04
14	3.98E-04
15	3.47E-04
16	5.44E-05
17	5.55E-05
18	5.64E-05
19	5.70E-05
20	5.73E-05

Table 8 – Total amount of substance leached from landfill (Qleach_landf) in year *i* for *i* = 1…Tutil+5 ($kg.yr^{-1}$)

Year (*i*)	Qleach_landfi
1	1,71E-04
2	4,46E-04

3	9,67E-04
4	1,64E-03
5	2,40E-03
6	3,19E-03
7	3,96E-03
8	4,65E-03
9	5,22E-03
10	5,63E-03
11	5,87E-03
12	5,93E-03
13	5,83E-03
14	5,58E-03
15	5,21E-03
16	8,70E-04
17	9,44E-04
18	1,02E-03
19	1,08E-03
20	1,15E-03

END CALCULATIONS

In order to calculate the predicted exposure for groundwater and for the sewage treatment plant, the amounts of substance transported to the STP, penetrating into the subsoil of the landfill and the concentration of chloralose in percolating water were determined, as described on the following tables.

Table 9 – Amount of substance leached in year *i* and transported to the STP (Qsubst_STP) for *i* = 1…Tutil+5 (kg)

Year (*i*)	Qsubst_STPi
1	1,63E-04
2	4,23E-04
3	9,19E-04
4	1,55E-03
5	2,28E-03
6	3,03E-03
7	3,77E-03
8	4,42E-03
9	4,96E-03
10	5,35E-03
11	5,57E-03
12	5,63E-03
13	5,54E-03
14	5,30E-03
15	4,95E-03
16	8,26E-04
17	8,97E-04
18	9,65E-04

19	1,03E-03
20	1,09E-03

Table 10 – Amount of substance leached in year *i* and penetrating into the subsoil of the landfill (Qsubst_soil) for *i* = 1…Tutil+5 (kg)

Year (*i*)	Qsubst_soili
1	8,56E-06
2	2,23E-05
3	4,84E-05
4	8,18E-05
5	1,20E-04
6	1,60E-04
7	1,98E-04
8	2,33E-04
9	2,61E-04
10	2,81E-04
11	2,93E-04
12	2,96E-04
13	2,91E-04
14	2,79E-04
15	2,61E-04
16	4,35E-05
17	4,72E-05
18	5,08E-05
19	5,41E-05
20	5,73E-05

Table 11–Concentration of substance in percolating water in year *i* (Csubst_perc) for *i* = 1…Tutil+5 (mg.L^{-1})

Year (*i*)	Csubst_perci
1	7,35E-07
2	2,00E-06
3	4,54E-06
4	8,06E-06
5	1,24E-05
6	1,75E-05
7	2,29E-05
8	2,85E-05
9	3,41E-05
10	3,94E-05
11	4,41E-05
12	4,82E-05
13	5,16E-05

14	5,41E-05
15	5,60E-05
16	5,80E-05
17	6,29E-05
18	6,77E-05
19	7,22E-05
20	7,64E-05

2.2.1 PEC FOR SEWAGE TREATMENT PLANT

For calculation of PECstp, the determination method included on TGD on Risk Assessment (2003) was performed. Hence, the concentration of chloralose in the influent of the STP is determined as follows:

$$Clocal_{inf} = \frac{Elocal_{water} \times 10^{6}}{EFFLUENT_{stp}}$$

Elocalwater was determined as the amount of substance leached and transported to the STP (Qsubst_STP). According to the TGD on Risk Assessment (2003), some characteristics of a municipal sewage treatment plant include a capacity of the local STP (CAPACITYstp) of 10,000 eq and an amount of wastewater per inhabitant (WASTEWinhab) of 200 L.d-1.eq-1. The total amount of wastewater produced in a year (EFFLUENTstp) would be:

$$EFFLUENTstp = CAPACITYstp \times WASTEWinhab \times 365 = 7.30 \times 10^{8}\ L.yr^{-1}$$

Clocalinf through the landfill life-cycle is described on the following table:

Table 12–Concentration of chloralose in untreated wastewater (Clocalinf) in year *i* for *i* = 1…Tutil+5 ($mg.L^{-1}$)

Year (*i*)	Clocalinfi
1	2,23E-07
2	5,80E-07
3	1,26E-06
4	2,13E-06
5	3,12E-06
6	4,16E-06
7	5,16E-06
8	6,06E-06
9	6,79E-06
10	7,33E-06
11	7,64E-06
12	7,72E-06
13	7,58E-06
14	7,26E-06
15	6,78E-06
16	1,13E-06
17	1,23E-06

18	1,32E-06
19	1,41E-06
20	1,49E-06

The concentration of the effluent of the STP is given by the fraction directed to effluent and the concentration in untreated wastewater as follows:

$$Clocaleff = Clocal\text{inf} \times Fstpwater$$

The tables included on appendix II of the TGD on Risk Assessment (2003) were taken into consideration in order to evaluate the fate of substance that enters the sewage treatment plant. Biodegradation of chloralose is not likely to occur. Since *log Kow = 0.85* and *log H = -3.2*, the total amount of substance is expected to remain in the water phase, i.e., *Fstpwater = 1*. Hence:

$$Clocaleff = Clocal\text{inf}$$

Assuming steady-state and complete mixing in all tanks, the effluent concentration approximates the really dissolved concentration in activated sludge, and:

$$PECstp = Clocaleff$$

PECstp through the landfill life-cycle is therefore reported on Table 15.

Table 13 – Predicted environmental concentration in sewage treatment plant (PECstp) in year *i* for *i* = 1…Tutil+5 ($mg.L^{-1}$)

Year (*i*)	PECstpi
1	2,23E-07
2	5,80E-07
3	1,26E-06
4	2,13E-06
5	3,12E-06
6	4,16E-06
7	5,16E-06
8	6,06E-06
9	6,79E-06
10	7,33E-06
11	7,64E-06
12	7,72E-06
13	7,58E-06
14	7,26E-06
15	6,78E-06
16	1,13E-06
17	1,23E-06
18	1,32E-06
19	1,41E-06
20	1,49E-06

2.2.2 PEC FOR SURFACE WATER

For the calculation of PECsurface water, a dilution factor of 10, as in accordance with the TDG on Risk Assessment (2003), is applied following discharge from the sewage treatment plant into surface water.

Table 14 – Predicted environmental concentration in surface water (PECsurface water) in year *i* for *i* = 1…Tutil+5 ($mg.L^{-1}$)

Year (*i*)	PECsurface wateri
1	2,23E-08
2	5,80E-08
3	1,26E-07
4	2,13E-07
5	3,12E-07
6	4,16E-07
7	5,16E-07
8	6,06E-07
9	6,79E-07
10	7,33E-07
11	7,64E-07
12	7,72E-07
13	7,58E-07
14	7,26E-07
15	6,78E-07
16	1,13E-07
17	1,23E-07
18	1,32E-07
19	1,41E-07
20	1,49E-07

2.2.3 PEC FOR GROUNDWATER

According to the TGD on Risk Assessment (2003), PECgroundwater can be derived from the predicted environmental concentration in porewater, PECsoil,porewater. Taking into consideration mobility of chloralose in soil ranges from moderately mobile to very mobile, it can be assumed, as a worst case scenario, that the concentration of chloralose in porewater is identical to its concentration in the leachate. The results are described on the following table.

Table 15 – Predicted environmental concentration in groundwater (PECgroundwater) in year *i* for *i* = 1…Tutil+5 ($mg.L^{-1}$)

Year (*i*)	PECgroundwateri
1	7,35E-07
2	2,00E-06
3	4,54E-06
4	8,06E-06
5	1,24E-05
6	1,75E-05

7	2,29E-05
8	2,85E-05
9	3,41E-05
10	3,94E-05
11	4,41E-05
12	4,82E-05
13	5,16E-05
14	5,41E-05
15	5,60E-05
16	5,80E-05
17	6,29E-05
18	6,77E-05
19	7,22E-05
20	7,64E-05

2.2.4 PEC FOR SEDIMENT

To avoid extensive testing, TGD on Risk Assessment (2003) advises that a log Kow of ≥ 3 can be used as a trigger value for sediment effects assessment. The log Kow for chloralose is 0.85 ± 0.03, therefore there is no requirement to carry out this assessment.

2.3 PEC IN AIR

Due to the low vapour pressure and low Henry's law constant it is not likely that chloralose will be present in the atmosphere at a relevant extent and if present in air it is expected to be quickly degraded by photo-oxidation.

2.4 PEC IN SOIL

There is no likely scenario for chloralose from Fast Action Mouse Killer to enter the terrestrial environment. The product is for indoor use only so there is no direct application. It is possible that a mouse treated indoors could wander to the external environment and contamination could occur via urine, faeces or the mouse carcass. Chloralose is fast acting and is metabolised quickly within the mouse body. This means that it is unlikely that a mouse would venture outdoors after consuming this product due to the fast acting nature and even if it did it is likely that the chloralose would have already been metabolised at least at some extension. The only other foreseeable route of entry to the terrestrial environment may be during disposal. Disposal of unused bait and collected rodent bodies will be to landfill. This has been previously considered in detail and, besides the fact that a fraction of the leachate can penetrate into the subsoil of the landfill, it's not likely that the substance remains in the soil due to its mobility properties.

2.5 NON COMPARTMENT SPECIFIC EXPOSURE RELEVANT TO THE FOOD CHAIN

2.5.1 PRIMARY POISONING

Fast Action Mouse Killer is used indoors and the opportunity for primary poisoning to non-targets is negligible. The product is presented in a tamper-resistant bait box as a non-spill formulation. It is therefore not attractive to granivorous passerine and corvid species. Birds such as sparrows (*Passer mantanus*), wood pigeons (*Columba palumbas*), pheasant (*Phasianus colchicus*) and chaffinch (*Fringilla coelebs*) would be unlikely to eat uncovered blocks. Birds have good eyesight and well-developed colour perception and a green block bait would bear no similarity to previously consumed foodstuffs. Foraging birds such as sparrows would not take particles larger than rice. The Fast Action Mouse Killer formulation is 1 cm in diameter.

Significant experience of the use of chloralose as a bird stupefying agent indicates that birds will refuse even their normal foodstuffs if there is any outward appearance of abnormality. The need to pre-bait over several days is a common requirement even where birds are known to be actively feeding rather than roosting. It is not intended or envisaged to market this rodenticide product in a form which could be attractive to birds.

2.5.2 SECONDARY POISONING

Chloralose affected target animals such as mice quickly succumb and do not generally exhibit the reduction in thigmotactic behaviour associated with anticoagulants. The tendency to "wander" away from their immediate protected pathways is reduced with chloralose, although their movement may be uncoordinated. It is proposed that this product is used indoors so any significant consumption of treated rodents outside is considered unlikely.

Studies in the UK of all species (including birds) examined in wildlife incidents in recent reports in 2001, and previously in 2000, showed no levels of chloralose found from kidney analysis at sub-lethal levels. In all cases, field investigations linked these residue levels to evidence of abuse using the 100% formulation illegally (Ref: Paragraph 104 page 30 WIIS 2001. UK.ACP Report and Paragraph 33 page 9 WIIS 2000 UK.ACP Report).
Reference should be made to ESD (2003), which states that the target animal, the mouse, will not eat large portions of the poison bait due to its rapid narcotic effect. Mammal predators may catch a poisoned mouse but with LD50 values no less than 100 mg/kg for cats and dogs, a secondary poisoning risk is considered negligible.

2.6 ENVIRONMENTAL EXPOSURE VIA METABOLITES

2.6.1 INDOOR LOCAL RELEASE ESTIMATES

Toxicokinetics studies in the rat have indicated that rapid metabolism of ingested chloralose occurs with approximately 60% of the administered dose of active substance being excreted in urine in the first 48 hours. A further 20% dose was found to be excreted in faeces. These studies also indicated that around 20% of the consumed dose remained within the animals as active substance or metabolites after 48 hours (it is the case that this 20% was held largely within the acidic environment of the stomach and small intestine where it would eventually degrade, even after death of the animal).
It is unlikely that chloralose as an active substance would remain at a significant level in rodent bodies and therefore, doesn't present a risk to the environment. Nevertheless, it is recognised that mice dying in their harbourages, which are dark, generally dry, cold and with little air movement, would remain intact for a period until "mummified" and ultimately decomposed. The resulting compounds would by that time have become degraded. In any event, mice that have died in their harbourages would not be accessible or provide a point of environmental contact or be availed of an exposure route. Also it is currently advised by regulatory authorities, that bodies found outside of harbourages should be collected and disposed of in the normal waste stream, as already discussed and considered within the landfill scenario.
The urine and faeces contained only 2.54 and 7.77% of chloralose after 6 hours and 24 hours, respectively. Mice are incontinent, constantly urinate and frequently defecate, but even so, such a small amount of active substance released indoors in this way would be an insignificant contribution of rodenticide to the environment as it would either remain and degrade, or more likely be washed or removed as solid waste or waste water, again ultimately transported to sewage water and thereby massively diluted.

2.6.2 EXTERNAL LOCAL RELEASE ESTIMATES

If the active substance were released to soil, either accidentally or by urine or faeces, chloralose is readily soluble, is not well absorbed in soils or sediment and would be sufficiently mobile to move down the soil profile. If the release of the active substance to soil was as a result of a mouse leaving its indoor harbourage and travelling and dying outside, then a small amount of chloralose would enter the environment through this route.

This is because the amounts that may need to be considered under the local release estimates are negligible due to the metabolism of chloralose shown in the toxicokinetics study discussed previously, and the initial amount of chloralose consumed per mouse.
It is accepted that little abiotic degradation has been shown to occur to date in the reported studies, and only a low level of biotic degradation but it's likely that the material is sufficiently "contained" with it being only used indoors, and subject to massive dilution when ultimately disposed of in landfill.
In any event, any release of rodenticide that may occur outside of buildings would ultimately wash to surface drains either when used on farms or at industrial premises. There would be little or no opportunity for the compound to enter agricultural soils or grasslands thereby not reaching the wider environment to any significant extent.

3 RISK CHARACTERISATION FOR THE ENVIRONMENT

According to the TGD on risk Assessment (2003), ESD (2003) and ESD for Biocides (RIVM, 2001), quantitative PEC/PNEC estimations are carried out, through comparison between predicted environmental concentrations (PEC) and the concentrations below which unacceptable effects on organisms will not occur (PNEC).

No risk characterisation for the manufacture and formulation of the product was performed since the environmental exposure from these lifecycle steps is expected to be low.

3.1 AQUATIC COMPARTMENT (INCL. SEDIMENT)

As described in above, the route of exposure to the environment being considered is through waste disposal of unspent product in landfill. Given the properties of the active substance, the most important route of environmental emission from landfill sites for chloralose would be leaching with water. Risk characterization for sewage treatment plant, surface water and groundwater will be performed.

3.1.1 RISK CHARACTERIZATION FOR STP

The calculated PNEC for microorganisms (PNECmicroorganisms) is presented in detail in section 1.3.2.

An assessment factor of 10 was applied on an EC10 value obtained from a respiration inhibition test:

$$PNEC_{microorganisms} = 70.29\ mg/L$$

Since the sanitary landfill model used for calculation of PEC's covers a period of 20 years (landfill utilization period of 15 years plus 5 years after closure), the PEC/PNEC ratios through the same period are presented in the following table:

Table 16 – PEC/PNEC ratios for STP

Year (*i*)	PEC/PNECstpi
1	3,17E-09
2	8,25E-09
3	1,79E-08
4	3,03E-08
5	4,44E-08
6	5,91E-08
7	7,34E-08
8	8,62E-08
9	9,66E-08

10	1,04E-07
11	1,09E-07
12	1,10E-07
13	1,08E-07
14	1,03E-07
15	9,65E-08
16	1,61E-08
17	1,75E-08
18	1,88E-08
19	2,00E-08
20	2,12E-08

3.1.2 RISK CHARACTERIZATION FOR SURFACE WATER

The calculated PNEC for surface water (PNECaquatic) is presented in detail in section 1.3.1.
An assessment factor of 1000 was applied on an EC50 value for the most sensitive species tested *Daphnia magna*. A geometric mean of 2 different EC50 values obtained from 2 validated studies was used to calculate PNECaquatic:

$PNECaquatic = 0.099\ \mu g/L$

Since the sanitary landfill model used for calculation of PEC's covers a period of 20 years (landfill utilization period of 15 years plus 5 years after closure), the PEC/PNEC ratios through the same period are presented in the following table:

Table 17 – PEC/PNEC ratios for surface water

Year (*i*)	PEC/PNECsurface wateri
1	2,25E-04
2	5,86E-04
3	1,27E-03
4	2,15E-03
5	3,15E-03
6	4,20E-03
7	5,21E-03
8	6,12E-03
9	6,86E-03
10	7,40E-03
11	7,71E-03
12	7,79E-03
13	7,66E-03
14	7,33E-03
15	6,85E-03
16	1,14E-03
17	1,24E-03
18	1,33E-03
19	1,42E-03
20	1,51E-03

3.1.3 RISK CHARACTERIZATION FOR GROUNDWATER

The concentration in groundwater is calculated for indirect exposure of humans to chloralose through drinking water. The maximum permissible concentration stated by Directive 80/778/EEC (amended by Directive 91/692/EEC and Directive 98/83/EC) is 0.1 μg/L.
As described in section 2.2.3, PECgroundwater was derived from the predicted environmental concentration in porewater, PECsoil,porewater, considering that a fraction of the leachate would penetrate into the subsoil of the landfill. The following table includes the ratios between the calculated PEC's and the above mentioned permissible limit, throughout the landfill life cycle:

Table 18 – Ratio between PECgroundwater and the maximum permissible concentration in drinking water

Year (*i*)	Ratio PEC / 0.1 μg/L
1	7,35E-03
2	2,00E-02
3	4,54E-02
4	8,06E-02
5	1,24E-01
6	1,75E-01
7	2,29E-01
8	2,85E-01
9	3,41E-01
10	3,94E-01
11	4,41E-01
12	4,82E-01
13	5,16E-01
14	5,41E-01
15	5,60E-01
16	5,80E-01
17	6,29E-01
18	6,77E-01
19	7,22E-01
20	7,64E-01

3.1.4 RISK CHARACTERIZATION FOR SEDIMENT

According to TGD on Risk Assessment (2003), since log Kow for chloralose is well below the trigger value of ≥ 3, effects assessment were not performed and an unaccepted risk is not expected to occur.

3.1.5 CONCLUSION

The PEC/PNEC ratios for the aquatic environment are all below 1, using worst case scenarios, and therefore the overall risk to the aquatic compartment is considered acceptable. Based on these values it is considered that there is no requirement for further information, testing or risk reduction measures for the aquatic environment in relation to the use of chloralose in the product for professional use.

3.2 ATMOSPHERE

Only a qualitative environmental risk assessment can be done for the air compartment due to lack of specific effect data. There are not expected to be any adverse effects in the atmosphere and there is negligible exposure of chloralose to the air. Given the zero level of exposure expected to the atmosphere from the use of chloralose in the rodenticide product for professional use there is no risk to the atmospheric compartment.

3.3 TERRESTRIAL COMPARTMENT

Under normal conditions of use, there will be no exposure of chloralose to the terrestrial environment, when it is used in the rodenticide product for professional use. There is no mechanism for the chloralose to be released directly into the terrestrial ecosystem because it is only for use indoors in discrete tamper resistant bait boxes. Other routes such as from rodent urine, faeces or carcasses and from disposal of unused bait have been considered and found to be negligible. This means that the use of chloralose in the rodenticide product for professional use will not affect the terrestrial environment.

3.4 NON COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN (SECONDARY POISONING)

An assessment of n-octanol/water partition coefficient, adsorption capacity and molecular mass indicated that chloralose is not likely to bioaccumulate in aquatic or terrestrial species, which leads to a negligible risk of secondary poisoning.

3.5 PBT ASSESSMENT

According to TGD on Risk Assessment (2003) PBT assessment is considered to be different from local and regional assessment, and its aim is to protect ecosystems where the risks are more difficult to estimate. These concerns occur when the substance can be both persistent for long periods and bioaccumulates in the biota, and can give rise to toxic effects after a greater time and at a greater distance than chemicals without these properties.

3.5.1 PERSISTENCE

The persistence of a substance reflects the potential for long-term exposure of organisms but also the potential for the substance to reach the marine environment and to be transported to remote areas.
Three different levels of information can be used:

experimental data on persistence in the marine environment
other experimental data
data from biodegradation estimation models

As chloralose is intended to be indoor use, the only available data refers to biodegradation, ready and inherent. According to results, chloralose is neither ready nor inherent biodegradable under test conditions. These results indicate according to screening criteria, that chloralose can be regarded as potentially persistent (P) or very persistent (vP) in marine environment.

3.5.2 BIOACCUMULATION

According to the TGD, the fulfilment of the B criterion should be based on measured data on bioconcentration in aquatic species. A substance is considered to fulfil the B criterion when the measured BCF on a wet weight basis exceeds a value of 2,000. A substance is considered very bioaccumulative when the BCF exceeds a value of 5,000.
For chloralose no measured data on bioconcentration in aquatic species is available. According to the TGD, if measured BCF values are not available, a substance is considered to potentially fulfil the B criterion if log Kow exceeds a value of 4.5. Chloralose has a determined log Kow of 0.85, which gives rise to a BCFfish value of 1.05, according to TGD equation 75 (despite the fact that log Kow is below its range of application). Therefore, it’s not considered that chloralose would potentially fulfil the B criterion.

3.5.3 TOXICITY

According to the TGD, a substance is considered to fulfil the toxicity criterion when the long-term NOEC for marine or freshwater organisms is less than 0.01 mg/L or the chronic avian NOEC is less than 30 mg/kg food. In the context of the PBT assessment, when data on chronic effects are not available, a substance is considered to be potentially toxic when the L(E)C50 to aquatic organisms is less than 0.1 mg/L. For chloralose, no long-term data for aquatic organisms is available just as any results from sub-chronic, chronic or reproduction avian toxicity tests. Regarding short-term results, chloralose is toxic to fish (the lowest acute test gave a 96h LC50 of 2.4 mg/L), very toxic to invertebrates (48h EC50 of 0.027 mg/L from the lowest acute test) and very toxic to algae (72h EC50 of 0.13 mg/L from the lowest acute test).
As a result, it can be concluded that chloralose fulfils the T criterion.

3.5.4 CONCLUSION

Chloralose can be regarded as potentially persistent (P) or very persistent (vP) in marine environment. Given its low log Kow, it's not considered that chloralose would potentially fulfil the B criterion. The T criterion is fulfilled due to the classification of chloralose as very toxic to aquatic organisms.
Since chloralose does not clearly fulfil the B criterion, further testing seems to be irrelevant for refining both P- and T-criteria. According to the TGD on Risk Assessment (2003), chloralose is not considered to be a PBT or a vPvB substance.